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03-CV-01324-CMP

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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

KONINKLIJKE PHILIPS ELECTRONICS
N.V. and PHILIPS ELECTRONICS NORTH
AMERICA CORPORATION,

Plaintiffs,

v.

CARDIAC SCIENCE, INC.,

Defendant.

CV03-1324

COMPLAINT FOR PATENT
INFRINGEMENT

JURY DEMAND

Plaintiffs, Koninklijke Philips Electronics, N.V. ("Royal Philips"), and Philips Electronics North America Corporation ("Philips Electronics") (together "Plaintiffs" or "Philips"), for their Complaint against Defendant, Cardiac Science, Inc. (hereinafter "Cardiac Science"), state and allege as follows:

PARTIES

1. Plaintiff Royal Philips is a Netherlands corporation with its principal place of business at Groenewoudseweg 1, 5621 BA Eindhoven, The Netherlands.

2. Plaintiff Philips Electronics is a Delaware corporation with its principal place of business at 1251 Avenue of the Americas, New York, New York, 10020-1104. One of Philips Electronics' divisions, Philips Medical Systems North America Company ("Philips Medical

COMPLAINT FOR PATENT INFRINGEMENT - 1

ORIGINAL

BYRNES & KELLER LLP
38TH FLOOR
1000 SECOND AVENUE
SEATTLE, WASHINGTON 98104
(206) 622-2000

1 Systems”), has a place of business at 22100 Bothell Everett Highway, P.O. Box 3003, Bothell,
2 Washington 98041-3003.

3 3. Upon information and belief, Defendant Cardiac Science is a Delaware
4 corporation with its principal place of business at 16931 Millikan Avenue, Irvine, California
5 92606.

6 **JURISDICTION AND VENUE**

7 4. This action arises under the patent laws of the United States (35 U.S.C. §§ 1 et
8 seq.). This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331
9 and 1338.

10 5. This Court has personal jurisdiction over Defendant pursuant to RCW § 4.28.185.

11 6. Venue lies in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b) as
12 Defendant is subject to personal jurisdiction, does business, and has committed acts of
13 infringement in this District.

14 **THE PATENTS IN SUIT**

15 7. On January 18, 2000, United States Patent No. 6,016,059 (“the ‘059 Patent”)
16 entitled “Defibrillator System Condition Indicator” was duly and legally issued to Heartstream,
17 Inc., as the assignee of inventor Carlton B. Morgan. A true and correct copy of the ‘059 Patent is
18 attached and made a part hereof as Exhibit A.

19 8. On March 9, 1999, United States Patent No. 5,879,374 (“the ‘374 Patent”)
20 entitled “External Defibrillator With Automatic Self-Testing Prior To Use” was duly and legally
21 issued to Heartstream, Inc., as the assignee of inventors Daniel J. Powers, David Cameron,
22 Clinton S. Cole, Thomas D. Lyster, Steven T. Mydynski, and Carlton B. Morgan. A true and
23 correct copy of the ‘374 Patent is attached and made a part hereof as Exhibit B.

24 9. On September 1, 1998, United States Patent No. 5,800,460 (“the ‘460 Patent”)
25 entitled “Method For Performing Self-Test In A Defibrillator” was duly and legally issued to
26 Heartstream, Inc., as the assignee of inventors Daniel J. Powers, David Cameron, Clinton S.

1 Cole, Thomas D. Lyster, Steven T. Mydyski, and Carlton B. Morgan. A true and correct copy
2 of the '460 Patent is attached and made a part hereof as Exhibit C.

3 10. On April 4, 2000, United States Patent No. 6,047,212 ("the '212 Patent") entitled
4 "External Defibrillator Capable Of Delivering Patient Impedance Compensated Biphasic
5 Waveforms" was duly and legally issued to Heartstream, Inc., as the assignee of inventors
6 Bradford E. Gliner, Thomas D. Lyster, Clinton S. Cole, Daniel J. Powers, and Carlton B.
7 Morgan. A true and correct copy of the '212 Patent is attached and made a part hereof as Exhibit
8 D.

9 11. On March 4, 1997, United States Patent No. 5,607,454 ("the '454 Patent")
10 entitled "Electrotherapy Method And Apparatus" was duly and legally issued to Heartstream,
11 Inc., as the assignee of inventors David Cameron, Thomas D. Lyster, Daniel J. Powers, Bradford
12 E. Gliner, Clinton S. Cole, and Carlton B. Morgan. A true and correct copy of the '454 Patent is
13 attached and made a part hereof as Exhibit E.

14 12. On January 7, 1997, United States Patent No. 5,591,213 ("the '213 Patent")
15 entitled "Defibrillator System Condition Indicator" was duly and legally issued to Heartstream,
16 Inc., as the assignee of inventor Carlton B. Morgan. A true and correct copy of the '213 Patent is
17 attached and made a part hereof as Exhibit F.

18 13. On May 8, 2001, United States Patent No. 6,230,054 ("the '054 Patent") entitled
19 "Apparatus For Controlling Delivery Of Defibrillation Energy" was duly and legally issued to
20 Agilent Technologies, Inc., as the assignee of inventor Daniel J. Powers. A true and correct copy
21 of the '054 Patent is attached and made a part hereof as Exhibit G.

22 14. On June 30, 1998, United States Patent No. 5,773,961 ("the '961 Patent") entitled
23 "Dynamic Load Controller For A Battery" was duly and legally issued to Heartstream, Inc., as
24 the assignee of inventors David Cameron, Daniel J. Powers, and Douglas H. Roberts. A true and
25 correct copy of the '961 Patent is attached and made a part hereof as Exhibit H.
26

1 15. On May 4, 1999, United States Patent No. 5,899,926 ("the '926 Patent) entitled
2 "Environment-Responsive Method For Maintaining An Electronic Device Such As An External
3 Defibrillator" was duly and legally issued to Heartstream, Inc. as the assignee of inventors
4 Dennis E. Ochs, Ian G. MacDuff, and Daniel J. Powers. A true and correct copy of the '926
5 Patent is attached and made a part hereof as Exhibit I.

6 16. On May 18, 1999, United States Patent No. 5,904,707 ("the '707 Patent) entitled
7 "Environment-Response Method For Maintaining An External Medical Device" was duly and
8 legally issued to Heartstream, Inc. as the assignee of inventors Dennis E. Ochs, Ian G. MacDuff,
9 and Daniel J. Powers. A true and correct copy of the '707 Patent is attached and made a part
10 hereof as Exhibit J.

11 **COMPLAINT FOR PATENT INFRINGEMENT**

12 17. Philips restates, realleges, and incorporates by reference the allegations set forth
13 in paragraphs 1 through 16.

14 18. Royal Philips is the owner of the '059 Patent, the '374 Patent, the '460 Patent, the
15 '212 Patent, the '454 Patent, the '213 Patent, the '961 Patent, the '926 Patent, and the '707
16 Patent by virtue of an assignment from Heartstream, Inc. to Hewlett Packard Corp., followed by
17 an assignment from Hewlett Packard Corp. to Agilent Technologies, Inc., followed by an
18 assignment from Agilent Technologies, Inc. to Royal Philips. Royal Philips is the owner of the
19 '054 Patent by virtue of an assignment from Agilent Technologies, Inc. to Royal Philips. The
20 aforementioned patents will hereinafter be referred to collectively as the "Patents-In-Suit." As
21 the owner of the Patents-In-Suit, Royal Philips is authorized and has standing to bring legal
22 action to enforce all rights arising under the Patents-In-Suit.

23 19. Philips Medical Systems makes and sells automatic external defibrillators.
24 Philips Medical Systems marks its automatic external defibrillator products in accordance with
25 the provisions of 35 U.S.C. § 287, disclosing to the public that the products are made under one
26 or more of the Patents-In-Suit.

1 20. Upon information and belief, Defendant Cardiac Science has made, used, sold,
2 offered for sale and/or imported, and continues to make, use, sell, offer for sale and/or import,
3 POWERHEART AED and SURVIVALINK AED (a.k.a. FIRSTSAVE AED) external
4 defibrillator products in this District and throughout the United States. Cardiac Science has
5 caused, and continues to cause, such defibrillator products to be used and sold in this District and
6 throughout the United States.

7 21. On July 30, 2002, Plaintiffs gave actual notice to Defendant Cardiac Science that
8 its POWERHEART AED and SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator
9 products infringe the '454, '212, '460, '374, and '059 patents under 35 U.S.C. § 287.

10 22. The '059 Patent relates generally to a method of automatic self-testing of a
11 defibrillator. Defendant's defibrillator products, including at least POWERHEART AED and
12 SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator products, infringe at least one
13 claim of the '059 Patent.

14 23. The '374 Patent relates generally to a defibrillator with automatic self-testing.
15 Defendant's defibrillator products, including at least POWERHEART AED and
16 SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator products, infringe at least one
17 claim of the '374 Patent.

18 24. The '460 Patent relates generally to a method of automatic self-testing of an
19 external defibrillator. Defendant's defibrillator products, including at least POWERHEART
20 AED and SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator products, infringe at
21 least one claim of the '460 Patent.

22 25. The '212 Patent relates generally to an external defibrillator that can deliver a
23 multiphasic shock. Defendant's defibrillator products, including at least POWERHEART AED
24 and SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator products, infringe at least one
25 claim of the '212 Patent.
26

1 26. The '454 Patent relates generally to a method and apparatus for delivering a
2 multiphasic shock. Defendant's defibrillator products, including at least POWERHEART AED
3 and SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator products, infringe at least one
4 claim of the '454 Patent.

5 27. The '213 Patent relates generally to a defibrillator with automatic self-testing.
6 Defendant's defibrillator products, including at least POWERHEART AED and
7 SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator products, infringe at least one
8 claim of the '213 Patent.

9 28. The '054 Patent relates generally to a method and apparatus for controlling
10 delivery of defibrillation energy. Defendant's defibrillator products, including at least
11 POWERHEART AED and SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator
12 products, infringe at least one claim of the '054 Patent.

13 29. The '961 Patent relates generally to a method and apparatus for optimizing battery
14 usage in a defibrillator. Defendant's defibrillator products, including at least POWERHEART
15 AED and SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator products, infringe at
16 least one claim of the '961 Patent.

17 30. The '926 Patent relates generally to a method of monitoring adverse
18 environmental conditions in a defibrillator. Defendant's defibrillator products, including at least
19 POWERHEART AED and SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator
20 products, infringe at least one claim of the '926 Patent.

21 31. The '707 Patent relates generally to a method of monitoring adverse
22 environmental conditions in a defibrillator. Defendant's defibrillator products, including at least
23 POWERHEART AED and SURVIVALINK AED (a.k.a. FIRSTSAVE AED) defibrillator
24 products, infringe at least one claim of the '707 Patent.
25
26

1 32. Upon information and belief, Defendant Cardiac Science has infringed and is
2 continuing to infringe one or more of the claims of each of the Patents-In-Suit, in violation of 35
3 U.S.C. § 271, to the damage and injury of Plaintiffs, and will continue to do so unless enjoined.

4 33. Upon information and belief, the acts of infringement by Defendant Cardiac
5 Science are willful, intentional, and in conscious disregard of Plaintiffs' rights under the Patents-
6 In-Suit.

7 34. As a result of Defendant Cardiac Science's infringement of the claims of the
8 Patents-In-Suit, Defendant has made and will continue to make unlawful gains and profits.
9 Further, Plaintiffs have been and will continue to be irreparably damaged and deprived of their
10 rights secured by the Patents-In-Suit due to the unlawful infringement by Defendant.

11 35. Plaintiffs have been and will continue to be deprived of revenue, profit, and gain
12 that they would otherwise have generated but for such infringement, and Defendant Cardiac
13 Science has caused and will continue to cause losses and damages in amounts that cannot be
14 determined with specificity except by an accounting, as well as irreparable losses and damages.

15 36. Plaintiffs are entitled to permanent injunctive relief, enjoining Defendant Cardiac
16 Science from further and continuing infringement of the claims of the Patents-In-Suit.

17 **RELIEF REQUESTED**

18 Whereof, Plaintiffs seek a judgment against Defendant as follows:

19 (a) Declaring that Defendant has infringed the Patents-In-Suit;

20 (b) Declaring that Defendant has induced infringement and engaged in contributory
21 infringement of the Patents-In-Suit;

22 (c) Awarding the Plaintiffs damages for Defendant's infringement of the Patents-In-
23 Suit, together with interest;

24 (d) Declaring the Defendant's infringement of the Patents-In-Suit is and has been
25 willful;
26

1 (e) Awarding Plaintiffs treble damages pursuant to 35 U.S.C. § 284 for Defendant's
2 willful infringement of the Patents-In-Suit;

3 (f) Enjoining Defendant from infringing the Patents-In-Suit in the future, where
4 appropriate;

5 (g) Declaring that the case is exceptional pursuant to 35 U.S.C. § 285, and awarding
6 the Plaintiffs attorneys' fees and costs in this action; and


7 (h) Awarding Plaintiffs such other and further relief as the Court may deem just and
8 proper.

9 **JURY DEMAND**

10 37. Pursuant to Fed. R. Civ. P. 38(b), Philips requests a trial by jury.

11 DATED this 19th day of June, 2003.

12 BYRNES & KELLER LLP

13
14 By 
15 _____
16 Bradley S. Keller, WSBA #10665
Keith D. Petrak, WSBA #19159

17 WILLKIE FARR & GALLAGHER

18 John M. DiMatteo
19 Steven H. Reisberg
20 Eugene L. Chang
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New York, New York 10019-6099
(212) 728-8661

21 **Attorneys for Plaintiffs Koninklijke Philips**
22 **Electronics and Philips Electronics North**
23 **America Corporation**

Exhibit A





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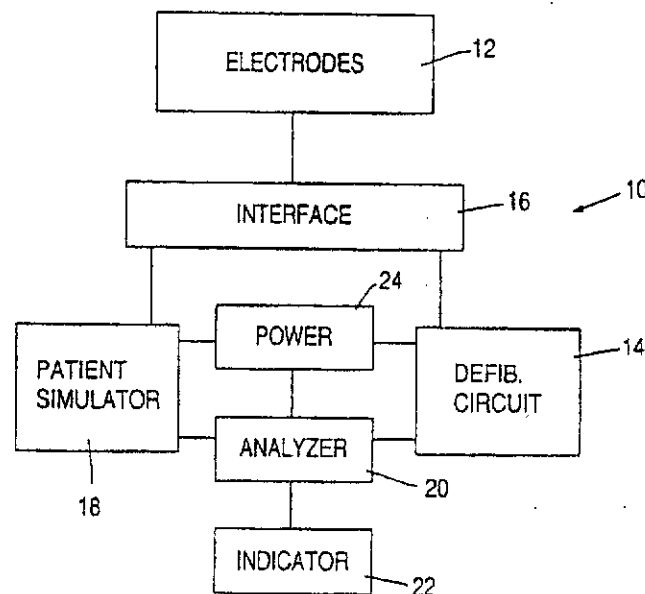
United States Patent [19]**Morgan**[11] **Patent Number:** 6,016,059[45] **Date of Patent:** Jan. 18, 2000[54] **DEFIBRILLATOR SYSTEM CONDITION INDICATOR**5,453,698 9/1995 Williams et al. 324/537
5,554,173 9/1996 Lenoire 324/149[75] **Inventor:** Carlton B. Morgan, Bainbridge Island, Wash.[73] **Assignee:** Heartstream, Inc., Seattle, Wash.[21] **Appl. No.:** 08/467,062[22] **Filed:** Jun. 6, 1995**FOREIGN PATENT DOCUMENTS**47386/93 3/1994 Australia
B-49189/93 6/1994 Australia
0472411 A1 2/1992 European Pat. Off.
0551746 A2 7/1993 European Pat. Off.
2172681 9/1973 France
2712352 A1 9/1978 Germany**OTHER PUBLICATIONS**Bennett, et al. "Portable Defibrillator-Monitor for Cardiac Resuscitation" *Hewlett-Packard Journal* pp. 22-27 (Feb. 1982).Blomfield "A cost effective defibrillator analyser" *Australian Physician & Engineering Sciences in Med.* 11(2):116-117 (1988).*Primary Examiner*—Maura Regan**Related U.S. Application Data**

[62] Division of application No. 08/063,631, May 18, 1993, abandoned.

[51] **Int. Cl.** G01R 27/26[52] **U.S. Cl.** 324/556[58] **Field of Search** 324/537, 127, 324/556; 128/706; 607/6-8[56] **References Cited****U.S. PATENT DOCUMENTS**3,747,605 7/1973 Cook 324/142
3,798,542 3/1974 Dempsey 324/133
3,983,476 9/1976 Konopasek 324/115
4,628,935 12/1986 Jones et al.
5,097,830 3/1992 Eikefjord 128/772
5,201,865 4/1993 Kuehn 128/772
5,231,987 8/1993 Robson
5,384,544 1/1995 Fugstad et al. 324/678
5,399,980 3/1995 Rashford 324/678[57] **ABSTRACT**

A defibrillator and electrode system that gives the user a visible and/or audible indication of the condition of the electrodes and other parts of the defibrillator system prior to deployment of the electrodes and use of the defibrillator. In a preferred embodiment of the method of this invention, a patient simulation and analyze circuit within the defibrillator periodically tests the condition of the system and provides the user with a visual indication of the system's condition.

11 Claims, 6 Drawing Sheets



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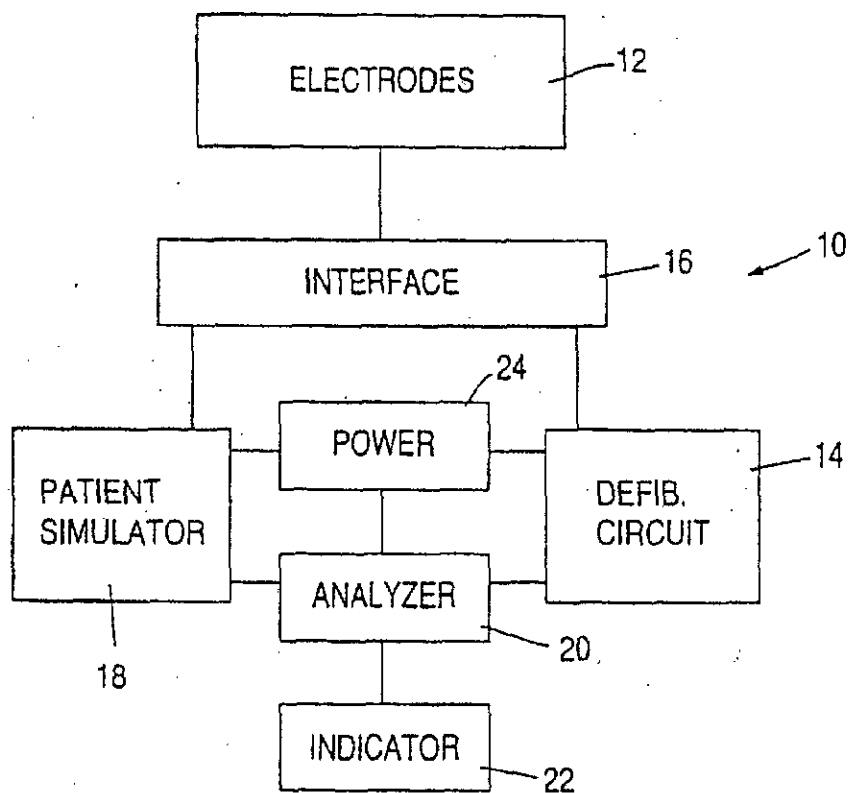


FIG. 1

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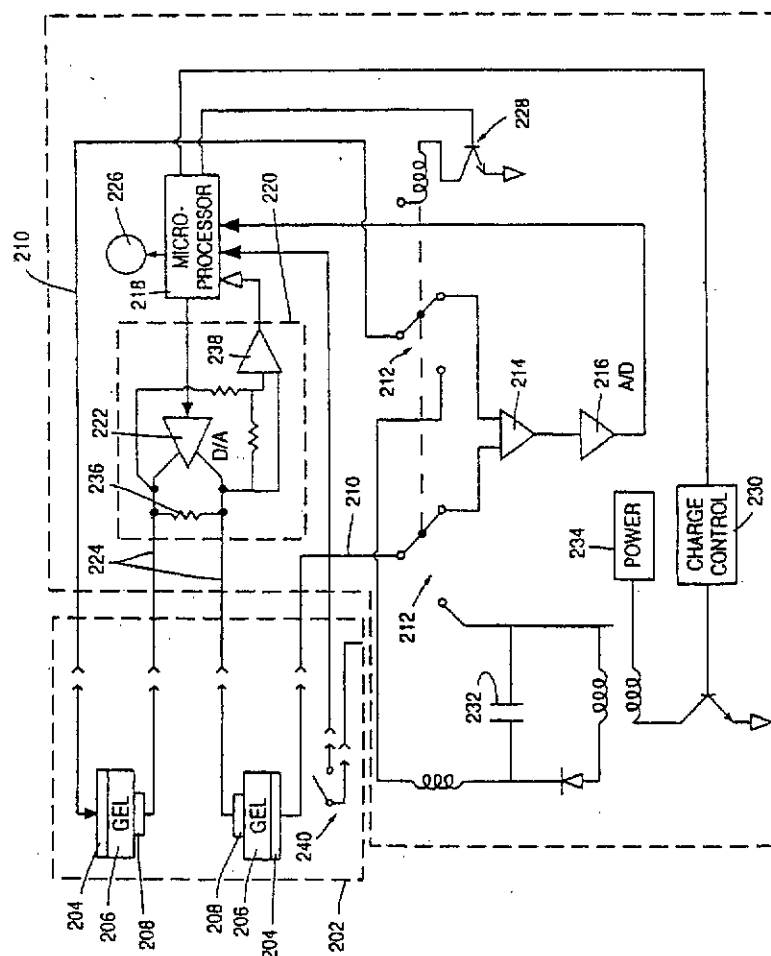


FIG. 2

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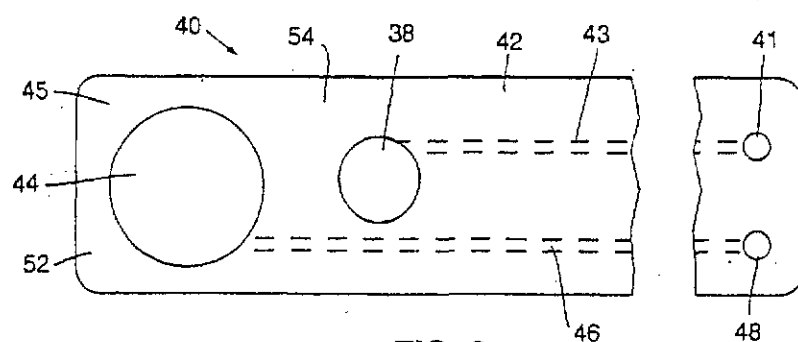


FIG. 3

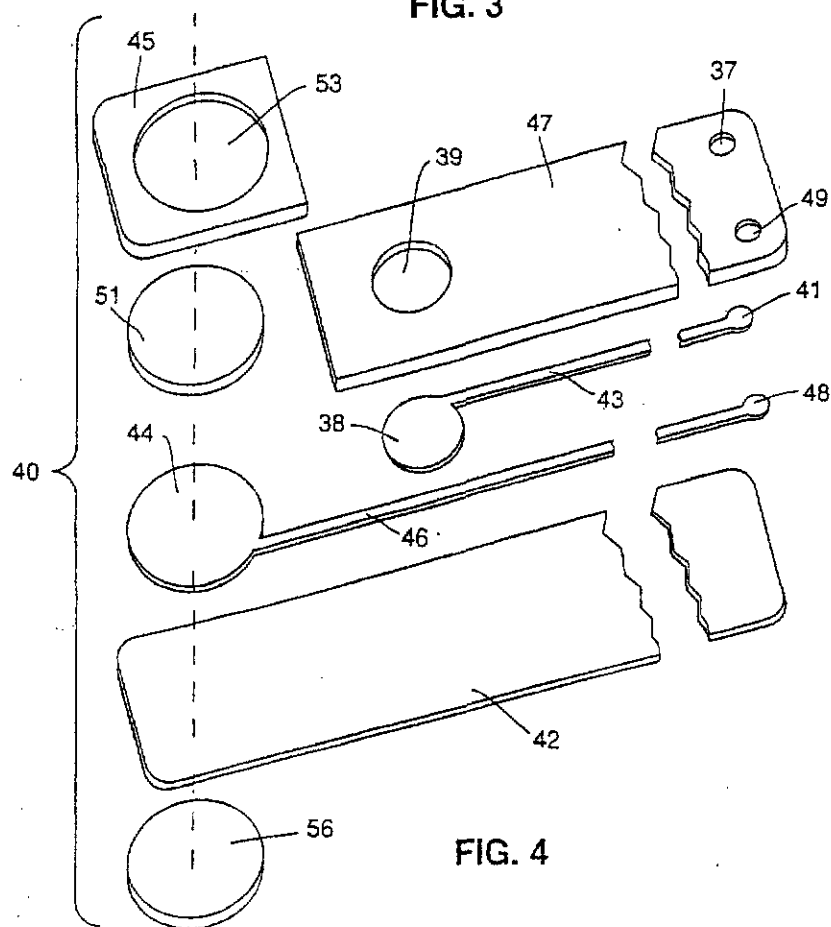


FIG. 4

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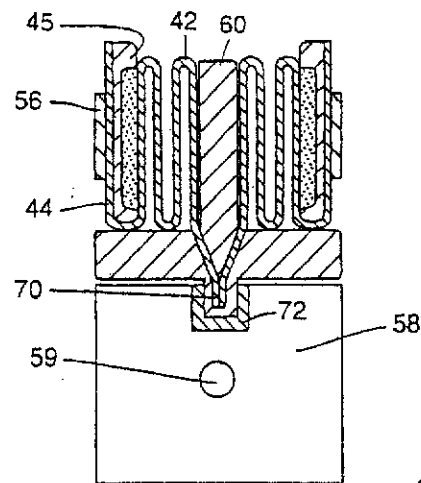


FIG. 5

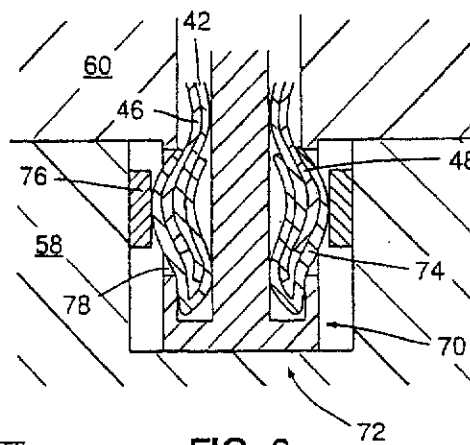


FIG. 6

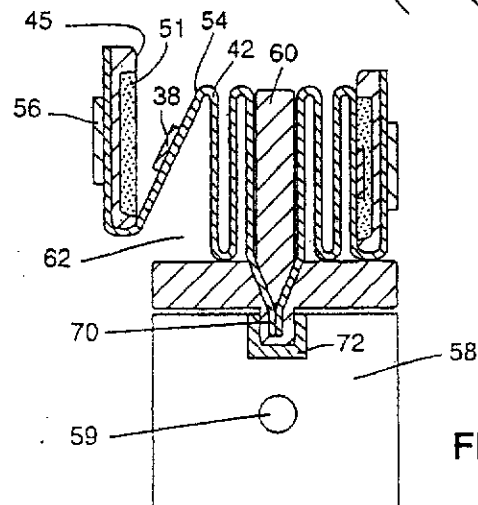


FIG. 7

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6,016,059

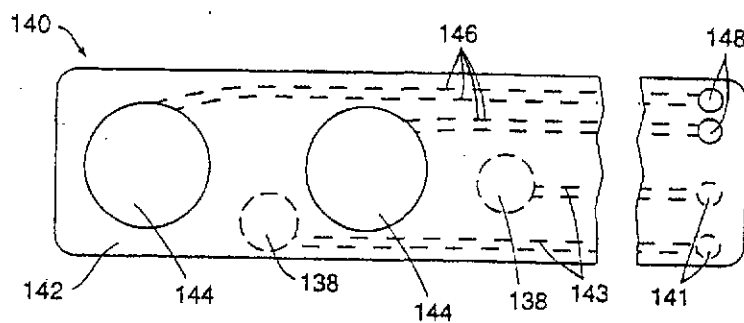


FIG. 8

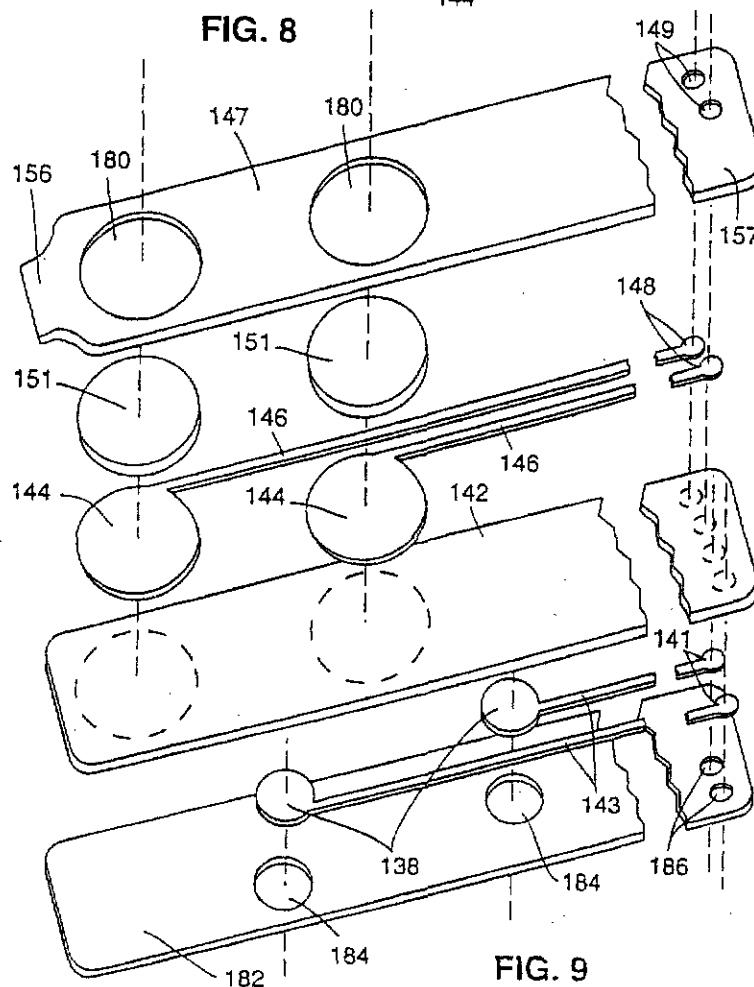


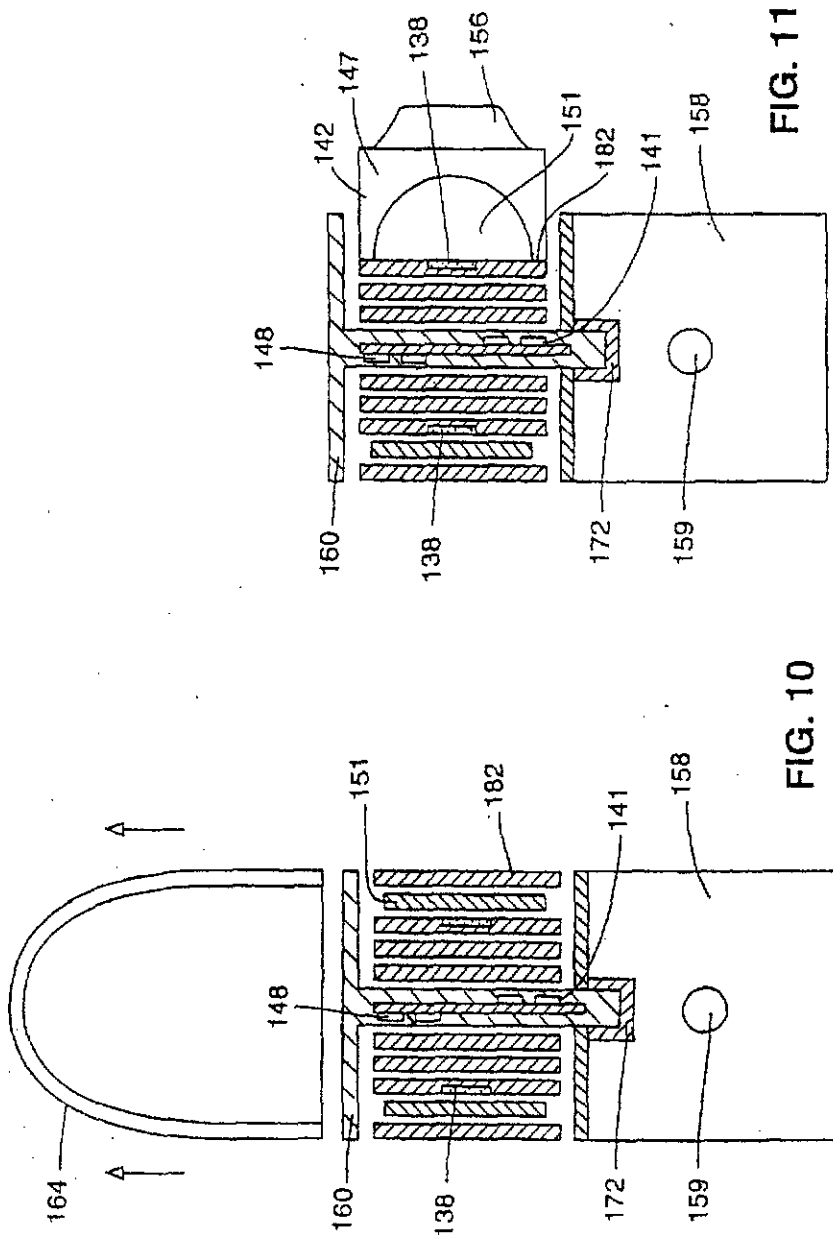
FIG. 9

U.S. Patent

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DEFIBRILLATOR SYSTEM CONDITION INDICATOR

This appln is a Division of Ser. No. 08/063,631 filed May 18, 1993, abnd.

BACKGROUND OF THE INVENTION

This invention relates generally to a method and apparatus for testing medical electrode systems and, in particular, to a method and apparatus for testing the operating condition of defibrillators and defibrillator electrodes and for providing the user with an indication of the system's condition.

Defibrillators apply voltage pulses to a patient's heart in response to a life-threatening condition such as cardiac arrest. External defibrillators deliver the voltage pulse through a pair of electrodes placed on the patient's chest or back by the attending medical personnel. The primary components of a defibrillator system are the defibrillator, which provides the voltage pulse, and the electrodes, which deliver the voltage pulse to the patient.

Prior art external defibrillator electrodes consist of a paddle having an electrode face electrically connected to the defibrillator by a cable. A conductive gel on the electrode face lowers the electrical resistance between the electrode and the patient. Disposable defibrillator electrodes are typically packaged with the gel pre-applied to the electrode face. Adhesive holds the electrodes in place on the patient. With standard reusable electrodes, on the other hand, the user must apply the gel before placing the electrodes on the patient. Handles on the back side of the electrode paddles enable the user to place the electrodes at the desired sites on the patient to hold the electrodes against the patient's skin.

SUMMARY OF THE INVENTION

One drawback of prior art defibrillator systems is the number of steps required to deploy the electrodes. Because defibrillators are used primarily in emergency situations, deployment and operation of defibrillator electrodes should be quick, easy and reliable. Prior art disposable defibrillator electrodes, however, require the following steps for deployment prior to delivery of the defibrillation pulse: connection of a cable to the defibrillator; inevitably, untangling of the cable; removal of the electrodes from their package; removal of the release liner covering the conductive gel over each electrode face and any adhesive surrounding the electrode; visual inspection of each electrode to determine whether it is usable; and application of the electrodes to the patient. Each of these steps takes time, and time is of the essence when trying to save a patient's life.

Furthermore, if a visual inspection or actual defibrillation attempt shows that either electrode is inoperative due to deterioration of the conductive gel, a broken conductor in the cable, a broken connection between the cable and the electrode, etc., then the deployment process must begin again, wasting even more time. What is needed, therefore, is a defibrillator system providing an indication of the condition of the defibrillator and defibrillator electrodes before deployment and placement on the patient.

Patient simulation units are available to test the operation of external defibrillators. Typically, the defibrillator output cable, i.e., the conductors leading to the electrodes, is connected to the simulation unit input. The defibrillator is then discharged as if the cable were attached to electrodes mounted on a patient. The simulation unit measures the defibrillator output pulse and gives an indication of the operating condition of the defibrillator. Because the defibril-

lator electrodes are not part of the test circuit, however, the simulation unit does not give any indication of electrode condition. Moreover, performing the test with patient simulation units adds to the burden of highly paid medical personnel, thereby raising the costs of the patient's care. What is needed, therefore, is a defibrillation system condition indicator that tests the electrodes and perhaps other parts of the defibrillator system automatically while the defibrillator is not in use.

This invention provides a defibrillator and electrode system that gives the user a visible and/or audible indication of the condition of the electrodes and other parts of the defibrillator system prior to deployment of the electrodes and use of the defibrillator. In a preferred embodiment of the method of this invention, a patient simulation and analyzer circuit within the defibrillator periodically tests the condition of the system and provides the user with a visual indication of the system's condition. One preferred embodiment of an electrode system useful for practicing this invention comprises a flexible substrate having a folded, undeployed position and an extended, deployed position. The substrate supports an electrode, an electrode tester conductive pad, and the electrical connections between the defibrillator and the electrode and between the conductive pad and the patient simulation and testing circuit. In its undeployed position, the electrode contacts the conductive pad to complete a circuit from the defibrillator, through the electrode to the patient simulation circuit.

In another preferred embodiment of an electrode system, the flexible substrate has a rolled or wound undeployed position and an unrolled or extended deployed position. The substrate supports a pair of electrodes, a pair of electrode tester conductive pads, and the electrical connections between these elements and the defibrillator and patient simulation circuits. In the substrate's undeployed position, the electrodes contact their respective conductive pads to complete a circuit from the defibrillator, through the electrodes to the patient simulation circuit.

The invention is explained in more detail below with reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a block diagram of a defibrillator system according to this invention.

FIG. 2 is a schematic circuit diagram of the defibrillator system of this invention.

FIG. 3 is an elevational view of an electrode system according to a preferred embodiment of this invention.

FIG. 4 is an exploded view of the electrode of FIG. 3.

FIG. 5 is a side cross-sectional view of a defibrillator electrode system according to a preferred embodiment, prior to deployment.

FIG. 6 is a cross-sectional view of a connector between an electrode system and an instrument.

FIG. 7 is a side cross-sectional view of the defibrillator electrode system of FIG. 5 with one electrode partially deployed.

FIG. 8 is an elevational view of an alternative embodiment of the electrode system of this invention.

FIG. 9 is an exploded view of the electrode system of FIG. 8.

FIG. 10 is a side cross-sectional view of the embodiment of FIG. 8, prior to deployment.

FIG. 11 is a side cross-sectional view of the electrode system of FIG. 10 with the electrodes partially deployed.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 is a block diagram demonstrating the method and apparatus of this invention as applied to a defibrillator system. The defibrillator system 10 includes two or more electrodes 12 selectively connected to a standard defibrillator circuit 14 through an electrode interface 16. The defibrillator circuit applies a therapeutic voltage or current pulse to a patient through the electrodes under conditions controlled by logic within or associated with the circuit. The defibrillator may also receive information regarding the patient's heart activity from the electrodes in the form of ECG signals. The electrodes may be configured as described below or, alternatively, may be any defibrillator electrodes known in the art.

A patient simulator 18 is also selectively connected to the electrodes through interface 16. A defibrillator system analyzer 20 connected to the defibrillator circuit 14 and the patient simulator 18 controls the operation of the defibrillator circuit 14 during a test procedure, receives test information through the patient simulator 18, analyzes the test information, and indicates the test results via indicator 22. A power source 24 supplies power to the system.

The operation of the system of FIG. 1 is as follows. The system may be used to test the ability of the defibrillator circuit and electrodes to deliver a defibrillation pulse to a patient. Conductors leading from at least two electrodes are connected to the defibrillator circuit via an electrode interface. The electrode surfaces themselves, i.e., the portion of the electrodes that would be mounted on the patient during normal operation of the defibrillator, are electrically connected to the patient simulator, also via the electrode interface. A defibrillator test pulse is delivered from the defibrillator circuit to the electrodes, and the effect of the test pulse is measured at the patient simulator by the analyzer. The test pulse may be a voltage pulse of any magnitude, including but not limited to voltage magnitudes used for actual defibrillation. In that case, the analyzer will measure the current flowing through the patient simulator. The test pulse may also be a current pulse of any magnitude, in which case the analyzer will measure the voltage across the patient simulator. Other suitable tests will be apparent to those skilled in the art.

If the current or voltage measured at the patient simulator by the analyzer is below a predetermined threshold, the analyzer activates the indicator to show that the defibrillator is not operable. The indicator may be a visible indicator such as a light or a written message on a display, an audible sound, or any other suitable means of communicating an inoperable condition to the user.

The system may also be used to test the response of the logic portion of the defibrillator circuit to a signal originating with the patient. As in the other test, conductors leading from at least two electrodes are connected to the defibrillator circuit via an electrode interface. The electrode surfaces themselves, i.e., the portion of the electrodes that would be mounted on the patient during normal operation of the defibrillator, are electrically connected to the patient simulator, also via the electrode interface. A signal substantially similar to an ECG signal derived from a patient in ventricular fibrillation is generated by the patient simulator and delivered to the defibrillator circuit via the electrodes and electrode interface. In normal operation, the defibrillator should deliver a defibrillation pulse to the patient in response to such an ECG signal.

The analyzer monitors the output of the defibrillator circuit logic to the test ECG signal. If the defibrillator circuit

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logic fails to indicate that a defibrillation pulse is required, then the analyzer activates the indicator to show that the defibrillator is not operable. Again, the indicator may be a visible indicator such as a light or a written message on a display, an audible sound, or any other suitable means of communicating an inoperable condition to the user.

The ECG test may also be used to determine the response of the defibrillator circuit to a normal (non-fibrillating) ECG signal from a patient. As in the other tests, conductors leading from at least two electrodes are connected to the defibrillator circuit via an electrode interface. The electrode surfaces themselves, i.e., the portion of the electrodes that would be mounted on the patient during normal operation of the defibrillator, are electrically connected to the patient simulator via the electrode interface. A signal substantially similar to an ECG signal derived from a patient with a normal ECG, i.e., not in ventricular fibrillation, is generated by the patient simulator and delivered to the defibrillator circuit via the electrodes and electrode interface. In normal operation, the defibrillator should not deliver a defibrillation pulse to the patient in response to such an ECG signal.

The analyzer monitors the output of the defibrillator circuit logic to the test ECG signal. If the defibrillator circuit logic indicates that a defibrillation pulse is required, then the analyzer activates the indicator to show that the defibrillator is not operable. As with the other tests, the indicator may be a visible indicator such as a light or a written message on a display, an audible sound, or any other suitable means of communicating an inoperable condition to the user.

An indication that the defibrillator is not operable as a result of any of these tests could mean that there is a problem with the electrodes, the conductive gel on the electrodes, the electrode interface, and/or the defibrillator circuit itself. Therefore, if any test fails, the user may replace the electrodes and/or the electrode interface and run the test again. If the test indicates that the defibrillator system is now operable, then the problem was in the electrodes and/or electrode interface.

The analyzer can also be used to monitor the power level of the battery in a battery-operated defibrillator. If the battery level falls below a predetermined minimum, the analyzer activates the indicator to show that the defibrillator is not operable because of low battery level.

The frequency of any of these tests may be chosen to meet the system's requirements. For example, the power required for the defibrillator pulse tests may be so high that the frequency of this test must be limited in order to preserve battery life in battery-operated defibrillators. At the other extreme, the analyzer could monitor battery level continuously.

FIG. 2 is a circuit schematic showing one way of implementing the principal elements of the defibrillator system of the preferred embodiment. The portion of the schematic corresponding to the electrodes and electrode interface blocks of FIG. 1 is enclosed by a dotted line 202 and is referred to as the electrode apparatus or electrode system. The electrode apparatus 202 includes a pair of electrodes 204, conductive gel layers 206 covering the electrodes, and a pair of test pads or contacts 208 shown here to be in electrical contact with gel layers 206.

Electrodes 204 connect to a standard defibrillator circuit via conductors 210. In the circuit state shown here, the system is set to monitor patient ECG signals as if the electrodes were attached to a patient. In this monitoring state, switches 212 send the incoming signal from the electrodes through a preamp 214 and an A/D converter 216

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for preprocessing before forwarding the signal to system microprocessor 218. Microprocessor monitors the received ECG signals and compares them to stored patterns or other criteria to distinguish normal patient ECG patterns from ECG patterns requiring action by the defibrillator system, as discussed below.

When configured as shown in FIG. 2, i.e., so that electrodes 204 are in electrical contact with test pads 208, the system is in test mode. The defibrillator system of this invention has a patient simulation and test circuit 220 to monitor the condition and integrity of the system prior to deployment of the electrodes and application of the electrodes to a patient. Periodically, microprocessor 218 sends a series of test signals to D/A converter 222, which converts the signals to their analog equivalent and transmits the signals to test pads 208 via conductors 224. Electrodes 204 retrieve the test signals as if the test signals were actual patient ECG signals and sends the signals back to the microprocessor through the ECG monitor circuit described above.

Preferably, the test signals are of at least two types: normal patient ECG waveforms, and ECG waveforms indicating a therapeutic pulse is required. The microprocessor analyzes the test signals as if they were actual patient ECG signals and decides whether or not to apply a therapeutic pulse to the electrodes. In ECG test mode, however, the actual pulse is not generated or applied. Rather, the microprocessor examines its own decision to determine if it was correct. If the outgoing ECG test signal from the microprocessor to the D/A converter was a normal ECG waveform and the microprocessor determines from the incoming test ECG signal that a therapeutic pulse is required, the system is faulty, and the microprocessor indicates the fault on a fault indicator 226. Likewise, if the outgoing ECG test signal from the microprocessor to the D/A converter was an ECG waveform indicating the need for a therapeutic pulse and the microprocessor determines from the incoming test ECG signal that a therapeutic pulse is not required, the system is faulty, and the microprocessor indicates the fault on a fault indicator 226. If, on the other hand, the microprocessor determines correctly the required course of action, the fault indicator is not activated.

If the system passes the ECG tests, it then performs a defibrillator test by generating a pulse through its normal pulse generating circuitry and sending the pulse to the electrodes 204. To initiate the pulse test, the microprocessor sends a charge command to a charge controller 230, which begins charging capacitor 232 in a known manner from power supply 234. When the charge on capacitor 232 has reached the required level (either the charge level required for normal operation or some other test charge level), switch relay 228 moves switches 212 to their other position. This switch position permits the pulse circuit to discharge the capacitor to deliver a damped sinusoidal shock to the electrodes.

The pulse transmitted by the electrodes through conductive gel layers 206 to test pads 208 is monitored by the test circuit 220 across a patient load simulator 236. The signal is reduced by a divider circuit and sent to microprocessor 218 via A/D converter 238. If the pulse received by the microprocessor does not meet predetermined criteria (such as voltage levels and signal waveform shape), the microprocessor indicates a system fault by activating fault indicator 226. So long as the system passes the tests, the tests are repeated periodically until the electrodes and their gel layers are removed from test pads 208 as determined by a deployment detector 240.

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FIGS. 3 and 4 show an electrode apparatus according to a preferred embodiment of this invention. As shown in FIGS. 3 and 4, the electrode apparatus 40 has a relatively stiff electrode body 45 attached to a flexible substrate 42 with a medical grade adhesive. In this embodiment, substrate 42 is a polymer such as polyester or Kapton, approximately 3 mils thick. The length of substrate 42 depends on the requirements of the application. Electrode body 45 is preferably made from a light-weight, closed-cell foam approximately 25 mils thick.

An electrode disk 44 is disposed within electrode body 45. Electrode disk 44 is preferably a circular piece of metal foil, such as 3 mil tin, approximately 80 cm² in area, attached to substrate 42 with a suitable medical grade adhesive. Electrode disk 44 is covered with a layer of conductive gel 51 in a known manner. The thickness of gel layer 51 is 25 mils to make its top surface approximately even with the surrounding electrode body surface. Medical grade adhesive is disposed in adhesive area 52 on the top surface of electrode body 45 surrounding the opening 53 for electrode disk 44.

A first conductor 46 and a first electrical attachment pad 48 are formed on, or attached to, flexible substrate 42. Conductor 46 and electrical attachment pad 48 are preferably 3 mil tin foil formed integrally with electrode disk 44 and attached to substrate 42 with adhesive. A second conductor 43, a second electrical attachment pad 41 and a test pad 38 are formed on, or attached to, substrate 42. Conductor 43, attachment pad 41 and test pad 38 are also preferably formed as an integral piece of metal foil attached to substrate 42 with adhesive.

An insulating cover 47 is adhesively attached over substrate 42 and conductors 43 and 46. Cover 47 has a silicon release coating on its top side. Openings 49 and 37 are formed in cover 47 so that attachment pads 48 and 41, respectively, can make electrical contact with a connector, as described below. An additional opening 39 is formed in cover 47 so that test pad 38 can make electrical contact with electrode 44 through gel 51, also as described below.

In FIGS. 5-7, a pair of the electrodes shown in FIGS. 3 and 4 are mounted in a retainer for use with a defibrillator system. FIG. 5 shows the electrodes in a predeployment storage position. In this position, the flexible substrate 42 of each electrode is folded in an accordion fashion and placed in retainer 60.

The portion of substrate 42 on which the attachment pads 41 and 48 are located extends into a retainer connector area 70 for electrical attachment to a corresponding connector 72 on the defibrillator 58. FIG. 6 shows the details of one embodiment of the connectors for attachment pads 48 on the two electrode apparatuses. The same arrangement may be used for attachment pads 41.

Metal crimps 74 at the end of substrate 42 make electrical contact with attachment pads 41 and 48. The crimps 74 partially extend through openings 78 in the connector portion 70 of retainer 60. When the retainer connector portion is inserted into the connector portion of the defibrillator 58, crimps 74 make electrical contact with defibrillator contacts 76. The resilient action of the crimps 74 also provide the mechanical attachment of retainer 60 to defibrillator 58. The contacts 76 for each electrode and for each test pad are connected to the defibrillator electronics in a known manner.

The test pads 38, their associated conductors 43, their attachment pads 41, and the retainer connector 70 serve as the interface between the electrodes and a patient simulator circuit within defibrillator 58 during the defibrillator system tests described above. An indicator 59 such as a light or an audible annunciator is provided to inform the user of test results.

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Likewise, the conductors 46 and attachment pads 48 on the substrates are the interface between the electrodes and the defibrillator for delivery of the defibrillating voltage pulse and/or for monitoring of the electrical activity of the patient's heart during normal operation of the defibrillator. The positions of the electrode apparatus during the two operational modes will be explained with reference to FIGS. 5 and 7.

In the folded position shown in FIG. 5, the conductive gel 51 covering the electrode disk 44 of each electrode apparatus lies in electrical contact with its respective test pad 38. This contact closes the circuit going from one electrode through the patient simulation circuit to the other electrode so that the patient simulation tests can be performed.

Also, in the folded position shown in FIG. 5, the adhesive surrounding the electrode disk lies against an area 54 on the top surface of substrate 42. The top surface of substrate 42 is coated with a suitable release coating such as silicon in at least release area 54. The release coating enables the adhesive to peel away from substrate 42 during deployment of the electrode, as discussed below. The covering action of the substrate over the conductive gel also helps keep the conductive gel from drying out during storage. A handle 56 attached to the back side of electrode body 45 lies in position in which it can be grasped by a user during deployment of the electrodes.

FIG. 7 demonstrates deployment of the electrodes. As shown in FIG. 7, the user pulls electrode body 45 out of retainer 60 by grasping handle 56. As it moves out of the retainer, the electrode disk 44 and its conductive gel layer 51 peel away from substrate surface 42. Movement of the conductive gel layers 51 of the electrodes away from their respective test pads 38 breaks the circuit through the patient simulator. After removal from the retainer, the electrodes may be placed on a patient and used for monitoring the patient's heart activity and for applying therapeutic electrical pulses in the usual manner.

FIGS. 8-11 show an alternative embodiment of this invention. As shown in FIGS. 8 and 9, the electrode apparatus 140 has a flexible body or substrate 142, preferably formed from $\frac{1}{16}$ " closed cell foam. A backing layer 182 is attached to the underside of substrate 142 with a medical grade adhesive. Backing layer 182 may be formed from Tyvek or any other suitable material.

The underside of backing layer 182 is coated with a silicon release material. A pair of test pads 138 are adhesively attached to the top of backing layer 182 over a pair of openings 184 whose diameters are slightly smaller than the diameters of test pads 138. Openings 184 provide access to test pads 138 from the underside of backing layer 182.

Conductors 143 lead from test pads 138 to attachment pads 141. Openings 186 beneath attachment pads 141 have diameters slightly smaller than the diameters of attachment pads 141. Each set of test pad, conductor and attachment pad is preferably formed from a single piece of tin metal foil 3 mils thick.

A pair of electrodes 144 are adhesively attached to the top of substrate 142. Conductors 146 lead from electrodes 144 to attachment pads 148. Each set of electrode, conductor and attachment pad is preferably formed from a single piece of tin metal foil 3 mils thick. The surface area of each electrode is preferably 80 cm². A layer of conductive gel 151 covers each electrode. The thickness of the conductive gel layer is preferably 25 mils.

An insulating cover 147 is attached to the top side of substrate 142 with medical grade adhesive. Cover 147 has

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openings 180 for the electrodes and openings 149 for the attachment pads. Openings 180 have diameters slightly smaller than the diameters of their respective electrodes, and openings 149 have diameters slightly smaller than their respective attachment pads. Medical grade adhesive covers all of the top surface of cover 147 except for handle area 156 and connector area 157 for attachment of the electrode apparatus to a patient.

FIGS. 10 and 11 show the electrode apparatus of this embodiment mounted in a retainer. As seen in FIG. 10, prior to deployment, the electrode apparatus is wound around a spool-shaped retainer 160 mounted on top of a defibrillator 158. The portion of the electrode apparatus on which the attachment pads 141 and 148 are located extend into the center of the retainer spool where they make electrical connection with conductors (not shown) that connect to the defibrillator connector 172. The metal crimps shown in FIG. 6 may be used for this purpose. A protective cover 164 may be kept over retainer spool 160 until the electrodes are to be deployed.

In the undeployed state shown in FIG. 10, the conductive gel layers 151 and the adhesive coating on cover layer 147 face the inward toward the center of the retainer spool, and the release coating on the underside of backing layer 182 faces outward from the center. Thus, when the electrode apparatus is wound about itself, the conductive gel layers 151 and the adhesive coating on the cover layer lie against the silicon release coating of the backing layer 182. Also, the conductive gel layers 151 of each electrode lie in electrical contact against their respective test pads 138, as shown. This contact closes the circuit going from one electrode through the patient simulation circuit to the other electrode so that the patient simulation tests can be performed. An indicator 159 such as a light or an audible annunciator is provided to inform the user of test results.

To deploy the electrode apparatus of this embodiment, the protective cover 164 is removed, and the electrode apparatus is unwound from retainer spool 160 by pulling on handle or tab 156, as shown in FIG. 11. The release coating on backing layer 182 permits the conductive gel layers 151 and the adhesive on cover layer 147 to peel away. Movement of the conductive gel layers 151 of the electrodes away from their respective test pads 138 breaks the circuit through the patient simulator. The electrode apparatus is then applied to the patient and used for monitoring the patient's heart activity and for applying therapeutic electrical pulses in the usual manner.

The electrode apparatus and spool retainer remain attached to the defibrillator during use. The conductors 146 and attachment pads 148 provide the electrical connection between the electrodes 144 and the defibrillator for delivery of the defibrillating voltage pulse and/or for monitoring of the electrical activity of the patient's heart. After use, the retainer spool and the electrode apparatus it houses can be discarded and replaced with a new electrode set.

Modifications may be made to the described embodiments without departing from the scope of the invention. For example, other electrode configurations may be used with the test apparatus of this invention so long as an appropriate electrode interface is provided. When selecting electrode materials, it should be remembered that repeated tests could cause corrosion of the electrodes and/or test pads if the tests are not charge-balanced. In addition, while in the preferred embodiment the defibrillator runs the electrode integrity tests, it should be understood that a separate test unit may be used instead. The electrodes would then have to be discon-

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nected from the test unit and connected to a defibrillator before actual use. Also, while this invention has been described in the context of defibrillators and defibrillator electrodes, it should be understood that the invention applies to medical electrodes used with other instruments, such as ECG monitors.

Other modifications will be apparent to those skilled in the art.

What is claimed is:

1. A method for maintaining a defibrillator comprising the following steps:

periodically delivering a test pulse in a defibrillator from an energy source through conductors to a patient simulator within the defibrillator automatically without external activation;

analyzing a signal detected at the patient simulator to determine a condition of the defibrillator; and providing an indication of the condition of the defibrillator.

2. The method of claim 1 wherein the delivering step is controlled by a microprocessor.

3. The method of claim 1 further comprising the step of periodically delivering a test ECG signal in the defibrillator from a test signal source to a patient simulator within the defibrillator automatically without external control.

4. The method of claim 3 further comprising analyzing the test ECG signal to determine a condition of the defibrillator.

5. A method for maintaining a defibrillator prior to deployment of the defibrillator, the method comprising the following steps:

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(1) performing a defibrillator self-test automatically without external activation; and

(2) providing an indication of a result of the defibrillator self-test.

6. The method of claim 5 wherein step (1) is performed periodically.

7. The method of claim 5 wherein steps (1) and (2) are performed periodically.

8. The method of claim 5 wherein step (1) comprises delivering a test pulse from an energy source to a patient simulator within the defibrillator.

9. The method of claim 8 wherein step (1) further comprises analyzing a signal received at the patient simulator to determine a condition of the defibrillator.

10. The method of claim 5 wherein step (1) comprises delivering a test ECG signal from a test signal source.

11. A method for maintaining a defibrillator prior to deployment of the defibrillator, the method comprising the following steps:

(1) performing a plurality of self-tests automatically without external control, the self-tests comprising a first self-test being performed at a first frequency and a second self-test being performed at a second frequency; and

(2) providing an indication of a result at least one of the first and second self-tests.

* * * * *

Exhibit B

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United States Patent [19]
Powers et al.

[11] **Patent Number:** **5,879,374**
 [45] **Date of Patent:** **Mar. 9, 1999**

[54] **EXTERNAL DEFIBRILLATOR WITH
 AUTOMATIC SELF-TESTING PRIOR TO
 USE**

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[21] **Appl. No.:** 240,272

[22] **Filed:** May 10, 1994

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 63,631, May 18, 1993,
 abandoned.

[51] **Int. Cl.:** A61N 1/39

[52] **U.S. Cl.:** 607/5

[58] **Field of Search:** 607/4, 5, 3, 6-8;
 324/403, 415, 500, 512, 519, 523, 525,
 527; 330/2

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Primary Examiner—William E. Kamm

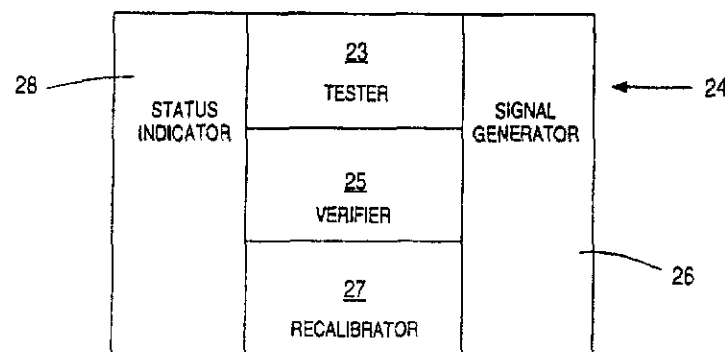
Attorney, Agent, or Firm—James R. Shay; Cecily Anne
 Snyder

[57]

ABSTRACT

A defibrillator with an automatic self-test system that
 includes a test signal generator and a defibrillator status
 indicator. The test system preferably performs functional
 tests and calibration verification tests automatically in
 response to test signals generated periodically and/or in
 response to predetermined conditions or events and indicates
 the test results visually and audibly. The invention also
 relates to a method for automatically determining and indi-
 cating a defibrillator's status without human intervention.

73 Claims, 7 Drawing Sheets



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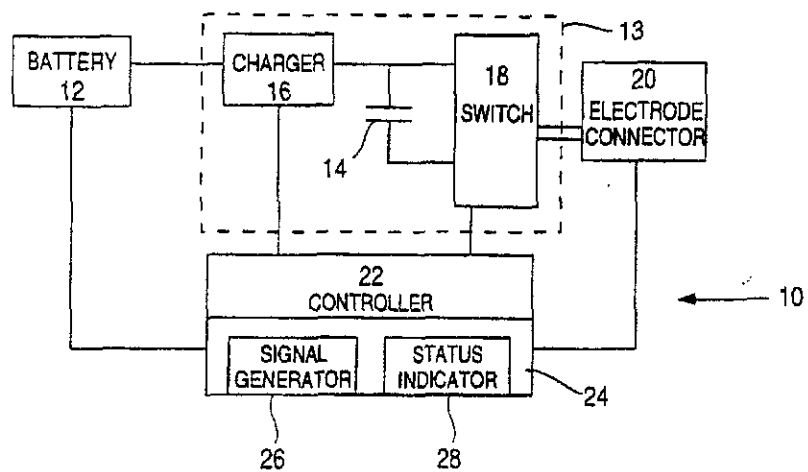


FIG. 1

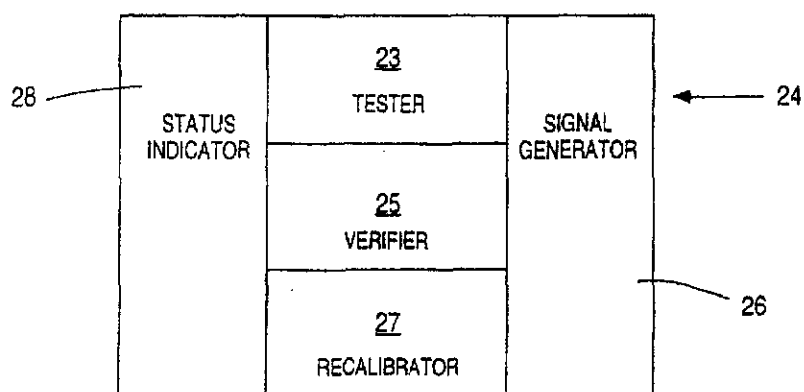


FIG. 2

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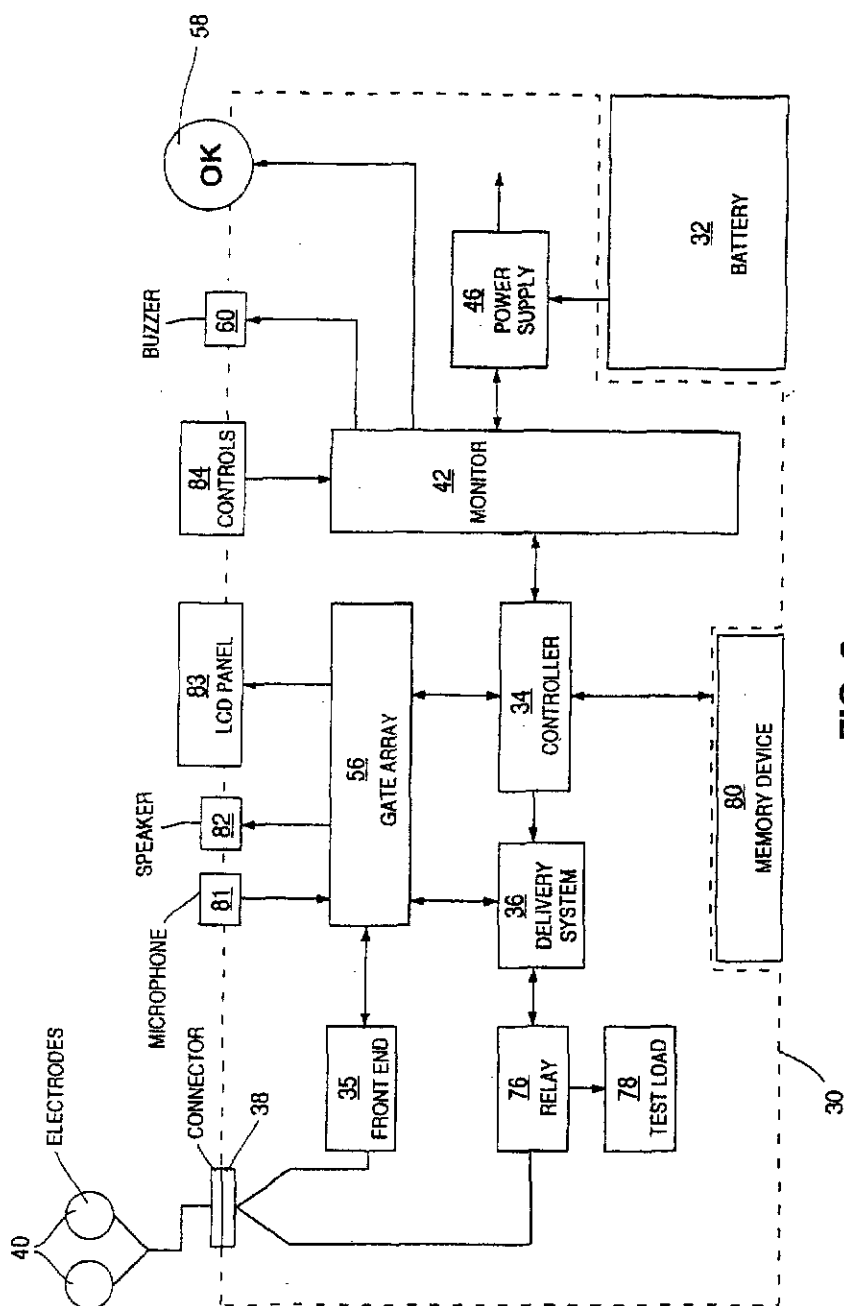


FIG. 3

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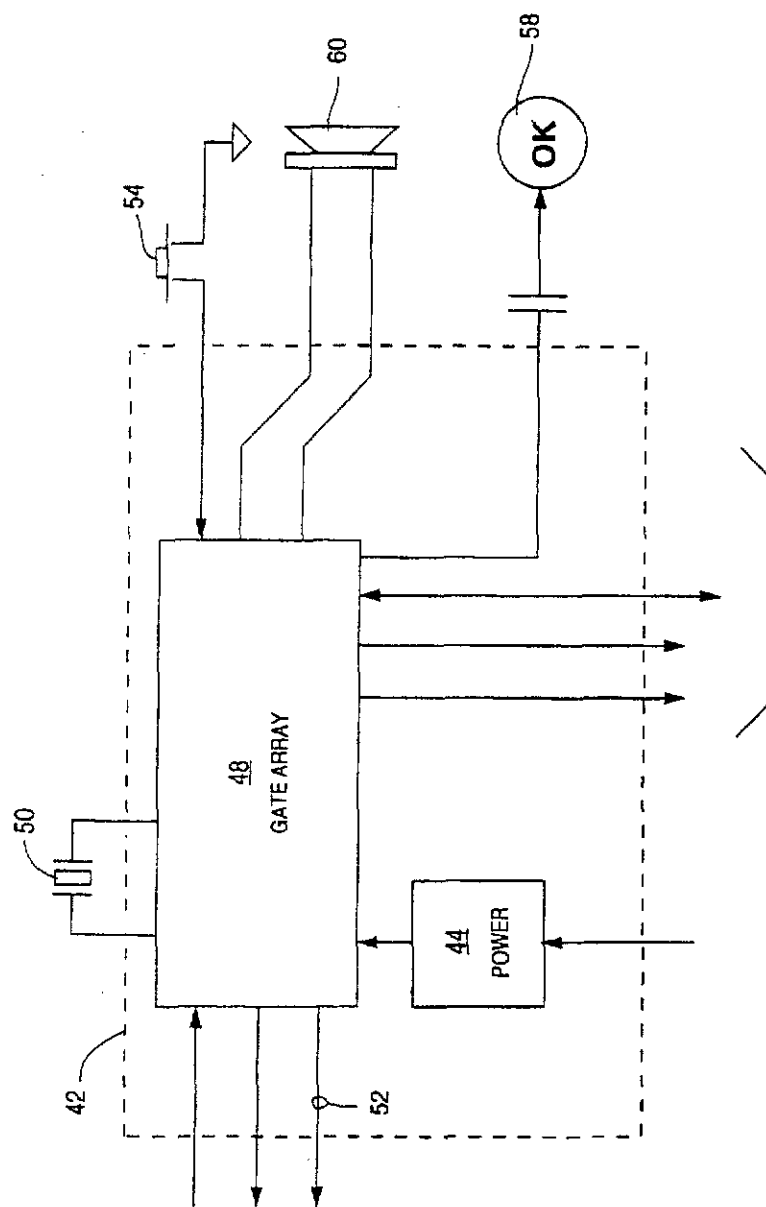


FIG. 4

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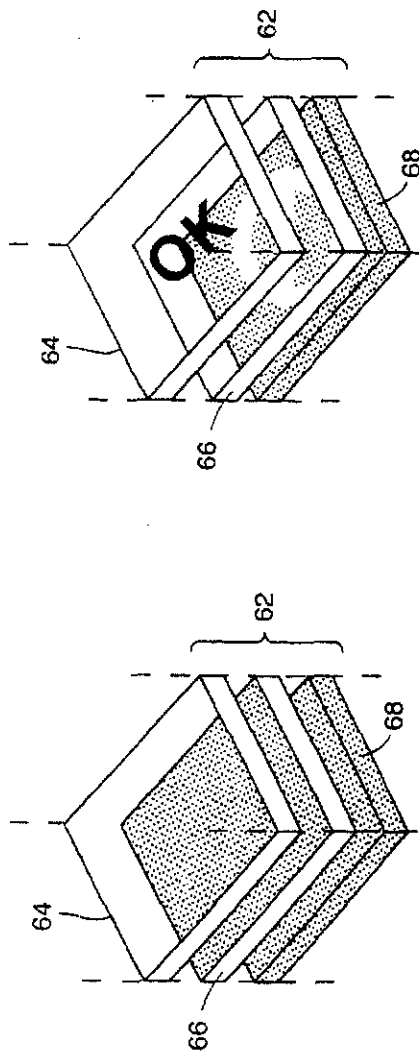


FIG. 5b

FIG. 5a

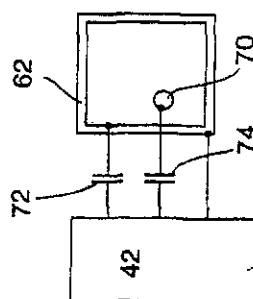


FIG. 5e

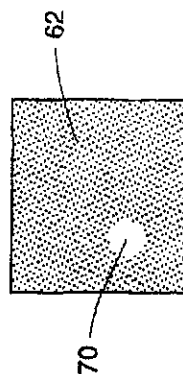


FIG. 5d

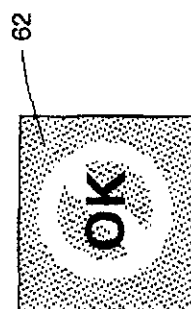


FIG. 5c

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TEST DESCRIPTION	BIT	WPST	MPST	DPST	POST	RUN TIME
CPU SELF-TEST	X	X	X	X	X	
SYSTEM GATE ARRAY	X	X	X	X	X	
SYSTEM MONITOR GATE ARRAY	X	X	X	X	X	
PROGRAM ROM CRC	X	X	X	X	X	
SYSTEM RAM CHECKSUM	X	X	X	X	X	
VIDEO RAM CHECKSUM	X	X	X			
DEVICE FLASH ROM CHECKSUM	X	X	X			
SYSTEM WATCH DOG	X	X	X	X	X	X
PCMCIA CARD VERIFY	X					
FRONT END GAIN	X	X	X	X		
ARTIFACT SYSTEM	X	X	X	X		
CMR CHANNEL	X	X	X	X		
DEFIBRILLATOR CONN/RELAY	X	X	X	X		
BATTERY SENSE CELL MEASUREMENT	X	X	X	X	X	X
BATTERY SENSE CELL LOAD MEASUREMENT	X	X	X	X	X	X
BATTERY STACK LOAD CHECK	X	X	X	X	X	X
POWER SUPPLIES CHECK	X	X	X	X	X	X
HV ISOLATION RELAY	X	X	X			
HIGH VOLTAGE DELIVERY SUBSYSTEM	X	X	X			
WAVEFORM DELIVERY						X
CALIBRATION STD. VOLTAGE	X	X	X	X	X	X
CALIBRATION STD. TIME	X	X	X	X	X	X
CALIBRATION STD. RESISTANCE	X	X	X			
STUCK BUTTON TEST	X	X	X	X		
BUTTON TEST	X					
LIGHT ALL LED'S	X				X	
LCD TEST PATTERN	X					
LCD BACKLIGHT VERIFY	X					
SPEAKER OUTPUT TEST	X				X	
PIEZO BEEPER TEST	X				X	

FIG. 6

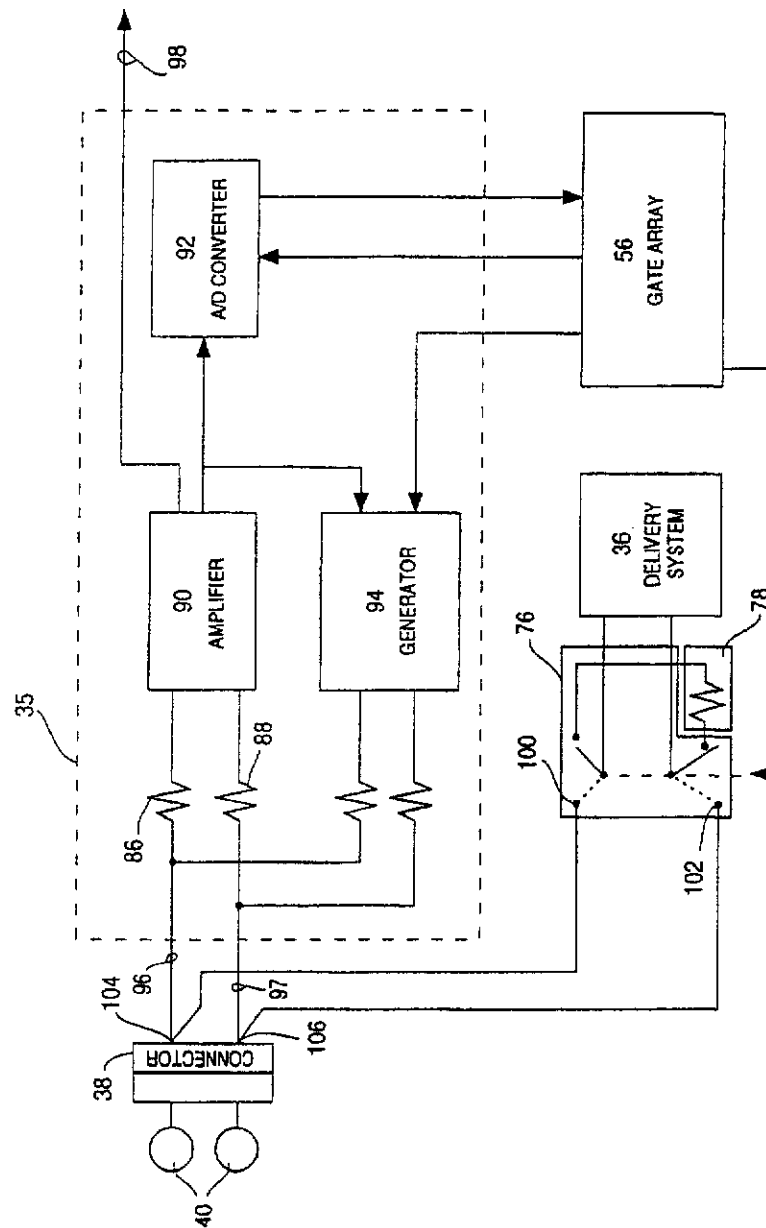


FIG. 7

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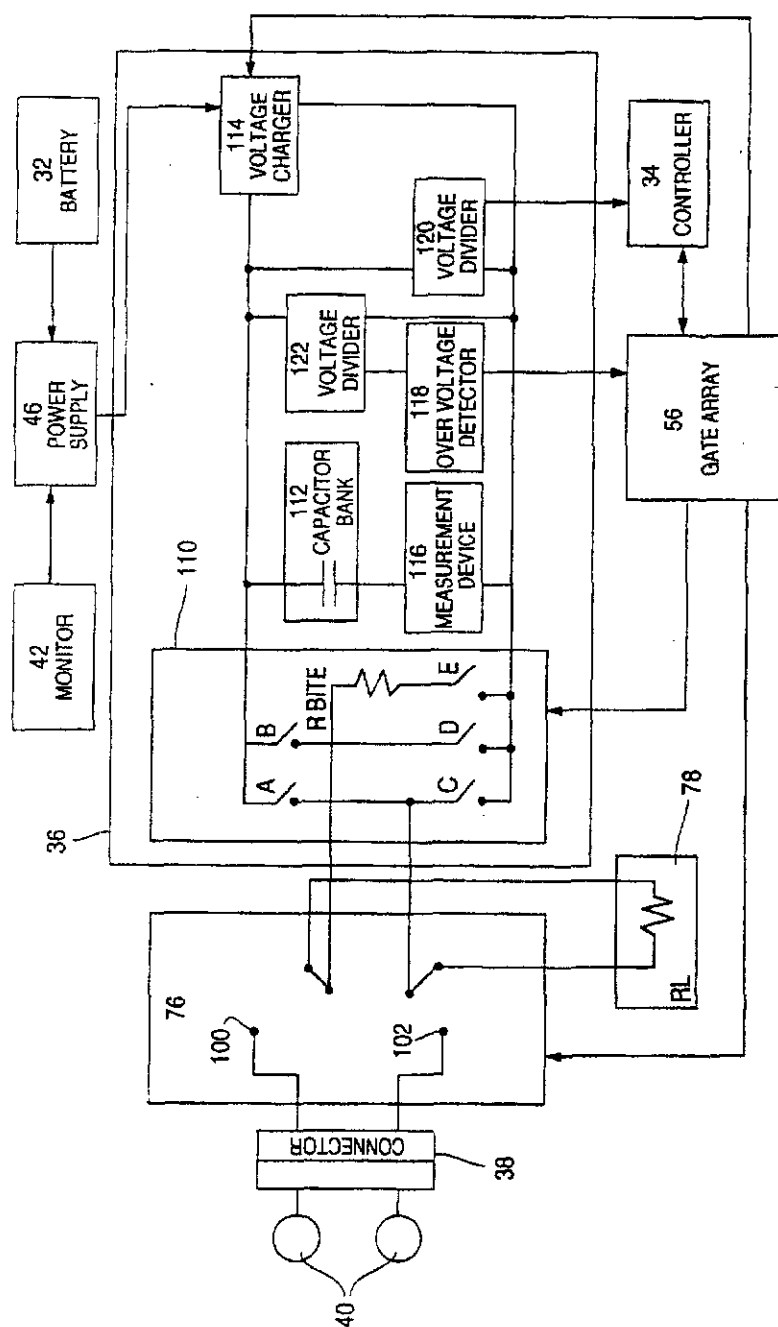


FIG. 8

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1 EXTERNAL DEFIBRILLATOR WITH AUTOMATIC SELF-TESTING PRIOR TO USE

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. patent application Ser. No. 08/063,631, filed May 18, 1993, now abandoned the disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates generally to a defibrillator system that performs periodic self-tests and, in particular, to a method and apparatus for performing periodic functional, calibration and safety tests in an automatic external defibrillator to verify that the defibrillator's components and operation are within preset specifications.

Prior art external defibrillators were used primarily in the hospital. In that environment, the frequency with which a particular defibrillator was used was relatively high, e.g., on the order of several times per week. Periodic verification tests for these prior art defibrillators typically amounted to a battery level test and a functional test in which the defibrillator was hooked to a test load and discharged. These tests were usually performed once per day or once per shift per manufacturer recommendations. Other tests, such as recalibration of internal circuit components by a biomedical technician, were performed less often, on the order of twice per year, also pursuant to manufacturer recommendations. Each of these maintenance tests for prior art defibrillators was initiated and performed by human operators.

SUMMARY OF THE INVENTION

While adequate for relatively frequently-used hospital-based defibrillators, prior art defibrillator test apparatuses and procedures are not optimal for use with portable defibrillators that are used less frequently. For example, defibrillators carried by emergency medical vehicles might need to be used only on a monthly basis. The burden of performing manual battery and performance tests on a daily basis could outweigh the benefits of carrying the infrequently-used defibrillator on the vehicle. The tests should therefore be performed by the defibrillator automatically.

Because the tests are performed automatically, the tests should be both accurate and reliable. The portable defibrillator's mobile environment could add to the frequency of defibrillator component failure, thus increasing the need for periodic tests. In addition, portable defibrillators could be exposed to environmental conditions (such as severe vibration, sudden impacts, heat or moisture) that require an immediate reevaluation of a defibrillator's operational status.

Also, the nature of the tests performed should be different in the portable defibrillator environment because of the relatively infrequent use of the defibrillators. Deterioration of system components over time could move the defibrillator out of its originally specified operating parameters. An infrequently used defibrillator should provide an operator with an indication not only of whether it will operate at all but also verify that the defibrillator meets its established specifications.

Defibrillators are used in emergency situations in which time is of the essence. The operational status of a particular

defibrillator as determined by the self-tests should be therefore readily apparent to an operator.

Finally, there is a need for a defibrillator that can automatically recalibrate itself if certain of its system components drift from their initial values. This automatic recalibration minimizes the burden on the defibrillator's operator or maintainer and lengthens the defibrillator's useful life.

This invention is a defibrillator with an automatic self-test system that includes a test signal generator and a defibrillator status indicator. The test system preferably performs functional tests and calibration verification tests automatically in response to test signals generated periodically and/or in response to predetermined conditions or events and indicates the test results visually and audibly. The invention also relates to a method for automatically determining and indicating a defibrillator's status without human intervention.

The invention is described in more detail below with respect to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram showing a defibrillator according to this invention.

FIG. 2 is a schematic diagram showing a testing system of a defibrillator according to this invention.

FIG. 3 is a block diagram showing some of the components of an external defibrillator according to a preferred embodiment of this invention.

FIG. 4 is a block diagram showing the system monitor of the embodiment of FIG. 3.

FIG. 5, parts (a)-(e) shows various aspects of a visual display according to the embodiment of FIG. 3.

FIG. 6 is a table showing groupings of external defibrillator self-tests according to a preferred embodiment of this invention.

FIG. 7 is a block diagram showing the interaction of an ECG front end and a testing system according to a preferred embodiment of this invention.

FIG. 8 is a block diagram showing the interaction of a high voltage delivery system and a testing system according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

This invention is a method and apparatus for automatically determining the status of a defibrillator, for displaying that status to a user or operator, and, for recalibrating certain defibrillator components. The invention is particularly useful for increasing the reliability of infrequently-used defibrillators by providing an indication of a defibrillator's operational status and by recalibrating the defibrillator, where possible, prior to any attempted use of the defibrillator.

In a preferred embodiment, the defibrillator automatically generates a test signal either (1) periodically in response to the passage of time or (2) in response to a specified event or condition, such as the insertion of a new battery or a manual power-up command from an operator. The test signal initiates a plurality of preset self-tests within the defibrillator. The self-tests may include functional tests that verify the operation of certain defibrillator components and subsystems. The self-tests may also include calibration verification tests that determine whether certain defibrillator components and subsystems are operating at preset

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specifications or within preset specification ranges. In addition, the defibrillator may automatically recalibrate certain components or subsystems in response to a calibration verification test.

No matter what test or collection of automatic self-tests the defibrillator performs, the defibrillator indicates its operational status as determined by the self-tests, such as through a visual display. The indication is preferably fail-safe so that a failure of the status indication mechanism itself will result in the indication of an inoperable defibrillator status.

FIG. 1 is a schematic representation of a defibrillator constructed and operated according to this invention. The defibrillator 10 includes a battery 12, a high voltage delivery system 13 (preferably consisting of a capacitor or capacitor bank 14, a capacitor charger 16 and a switching mechanism 18), an electrode connector 20 and a controller 22 that operates the charger and switching mechanism to deliver an electric shock from the capacitor to electrodes connected to the electrode connector or interface 20. The defibrillator has a testing system 24 including a test signal generator 26 and a defibrillator status indicator 28. The purpose of testing system 24 is to test the operational status of the defibrillator's components and to provide an indication of that status automatically in response to predetermined events or conditions and/or periodically on a preset schedule.

While the testing system 24 and controller 22 are shown in FIG. 1 as separate elements, they could be combined into a single element that performs all testing and operational control functions. In addition, the testing system 24 may also include components located within other defibrillator subsystems, such as within the high voltage delivery system. In any event, the testing system communicates with the tested defibrillator components and systems via communication channels to control the tests and to gather information about the status of the tested components. The testing system also communicates indicator control signals to the status indicator via communication channels as well.

FIG. 2 is a schematic drawing showing self-testing subsystems making up testing system 24 in the preferred embodiment. It is not necessary that a given defibrillator include each of the subsystems shown in FIG. 2. According to this invention, the defibrillator must include at least one automatic self-test that is initiated in response to a test signal generated either periodically or as a result of a specified event or condition.

Also, it is not necessary for the apparatus performing each test in each subsystem to be in the same physical location. FIG. 2 is a logical grouping and is not intended to be an actual drawing of a defibrillator or defibrillator subsystem.

Each self-test in each group of FIG. 2 responds to a test initiation signal from signal generator 26, and the result of each self-test in each group affects the status as indicated on status indicator 28. This collection of self-testing subsystems may be added to or subtracted from without departing from the invention. In addition, while there may be other tests performed by the defibrillator that do not meet these criteria, such tests form no part of this invention.

The first testing subsystem is the functionality tester 23. The self-tests performed by this subsystem test the operability and functionality of defibrillator components and/or subsystems. Examples include the testing of switches within the switching mechanism of the high voltage delivery system and the testing of registers within the defibrillator's controller.

The second testing subsystem is the calibration verifier 25. The self-tests performed by this subsystem determine

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whether certain defibrillator components and/or subsystems meet preset specifications. Examples include determining the capacitance of the defibrillator's capacitor and checking the response of the controller to capacitor voltage values.

The testing system also may include a recalibrator 27 that adjusts a component or subsystem of the defibrillator in response to a determination that the component or subsystem is no longer, or no longer operates, at a specified value or within a specified range of values. For example, parameters used by the defibrillator's controller to control operation of the high voltage delivery system may be changed to reflect changes in the values of defibrillator components.

The actual self-tests automatically performed by a defibrillator's testing system depend in part on the defibrillator's structure and in part on reliability goals set by the defibrillator's designer. Trade-offs may be made between the completeness of a given self-test (which adds to the reliability of the defibrillator product) and the cost of implementing a complete and accurate self-test. A particular implementation of a defibrillator and its self-testing system is described below. The discussion merely illustrates a preferred embodiment of the invention. Our invention covers other defibrillator designs and other collections of defibrillator self-tests as well.

FIG. 3 is a block diagram showing a preferred configuration for the defibrillator of this invention. Some of the elements are described in more detail further below. Defibrillator elements not specifically described in this application may be configured and operated in the manner described in U.S. patent application Ser. No. 08/227,553, now U.S. Pat. No. 5,607,454 "Electrotherapy Method and Apparatus," filed Apr. 14, 1994, the disclosure of which is incorporated herein by reference.

As shown in FIG. 3, external defibrillator 30 has a power source such as a removable battery 32, a controller such as CPU 34, and a high voltage delivery system 36 including a capacitor or capacitor bank and appropriate switches (not shown) to deliver a pulse of electrical energy to an electrode connector or interface 38 and then to a patient via electrodes 40. Delivery of the electrical pulse is controlled by CPU 34. A test and isolation relay 76 and a test load 78 are provided for reasons explained below.

An ECG front end system 35 acquires and preprocesses the patient's ECG signals through electrodes 40 and sends the signals to CPU 34 via a system gate array 56. System gate array 56 is a custom application specific integrated circuit (ASIC) that integrates many of the defibrillator's functions, such as display control and many of the instrument control functions, thereby minimizing the number of parts and freeing up main CPU time for use in other tasks. The system gate array could be replaced by discrete logic and/or another CPU, of course, as known in the art.

The external defibrillator shown in FIG. 3 also has a memory device 80 (such as a removable PCMCIA card or a magnetic tape), a microphone 81, a speaker 82, a LCD panel 83 and a set of illuminated push-button controls 84. None of these elements is critical to the present invention.

A system monitor mediates the external defibrillator's self-testing functions by watching for scheduled test times and unscheduled power-on events. The system monitor generates test signals periodically at scheduled times and in response to specified events. The system monitor is also responsible for operating a fail-safe defibrillator status indicator or display. The system monitor communicates test signals to the CPU via a communication channel, and the

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CPU controls and gathers information from tested defibrillator components via other communication channels, some of which pass through system gate array 56.

In the embodiment shown in FIG. 3, system monitor 42 is separate from CPU 34 so that power can be provided to the system monitor without powering any other part of the defibrillator. Thus, system monitor 42 has its own power supply 44 apart from the defibrillator power supply 46, as shown more specifically in FIG. 4. This dedicated power supply 44 draws approximately 30 microamps from battery 32 and is active whenever power is available from the battery. The dedicated system monitor power supply may also have its own battery apart from the main battery.

As shown in more detail in FIG. 4, the other major element of system monitor 42 is a low-power gate array 48. In this preferred implementation, gate array 48 is a 44-pin custom ASIC. Gate array 48 is preprogrammed to perform the functions of the system monitor. As an alternative, the system monitor could be implemented with a low power CPU and/or with discrete logic components.

Gate array 48 operates a 32.768 kHz crystal oscillator to provide the defibrillator testing system's scheduling function. The gate array divides the oscillator's frequency repeatedly to generate periodic (e.g., daily, weekly, monthly) test initiation signals. The system monitor also sends a 32.768 kHz clock signal out on line 52 to be used by the defibrillator system to perform other functions.

In addition to the periodic tests, certain defibrillator self-tests are performed rapidly in response to activation of the defibrillator's ON button (shown schematically as element 54 in FIG. 4) by an operator. Activation of the ON button 54 prompts the system monitor to generate a power-on test initiation signal.

The system monitor indicates the status of the defibrillator as a result of the periodic and power-on self-tests. The status indicator should be fail-safe so that the indicator will indicate an inoperable status if the system monitor should fail. The system monitor communicates control information to the status indicator through communication channels.

In a preferred embodiment, the system monitor 42 powers a status indicator consisting of a visual display 58 and a piezo buzzer 60 to indicate the operational status of the defibrillator to a user. As shown in more detail in FIG. 5, visual display 58 may be a multiple-part LCD 62 powered by the system monitor via AC-coupled drive 72. The top plate 64 of the LCD is a clear window with an "OK" symbol printed on its back. The middle plate 66 is an LCD shutter that is biased so as to be opaque when driven by the system monitor via drive 72. The bottom plate 68 has an international "Not" symbol on its top surface. Middle plate 66 also includes a separately addressable portion 70 driven by the system monitor via AC-coupled drive 74.

In operation, the system monitor 42 drives LCD shutter 66 only when confirmation of successful testing is received within an expected time window. The visual display would then appear as in FIG. 5, part (d). Failure to receive proper test confirmation within the allotted time window will cause the system monitor to cease issuing drive signals to shutter 66. Shutter 66 will then go transparent to superimpose an international "Not" symbol on the "OK" symbol in the LCD as shown in FIG. 5, part (e). The system monitor will also then begin powering a piezoelectric failure alert buzzer 60, preferably for 200 msec, every 10 sec, so long as there is power enough to do so.

The primary advantages of the visual display of the preferred embodiment are its low power requirements and

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the fact that it is powered by an AC signal rather than a DC signal. This latter point ensures the display's fail-safe nature, since the shutter of middle plate 66 cannot be maintained opaque without the active involvement of the system monitor generating the AC signal.

Separately addressable portion 70 serves as a positive indication (in addition to the fail-safe "OK" symbol) that the defibrillator has power and is functioning properly. Portion 70 blinks periodically through the alternating driving and releasing of the signal to portion 70 through drive 74.

In an alternative embodiment, an LCD shutter covering an "OK" symbol is driven open to display the "OK" symbol to indicate an operational defibrillator status. The shutter is permitted to close to cover the "OK" symbol to indicate that the defibrillator is not operational. Another alternative category of fail-safe indicators include electromechanical devices, such as those used for aircraft instrumentation.

In response to the generation of a test initiation signal, the system monitor commands the defibrillator's power system to turn on. The CPU then issues an appropriate series of commands to perform the required tests. The tests performed in response to the periodic and power-on test initiation signals are described in more detail further below with reference to the table shown in FIG. 6.

FIG. 6 shows the scheduling of some of the tests that can be performed by the self-test system of this invention. Some of the tests are performed when a battery is inserted, some are performed daily, some are performed weekly, some are performed monthly, some are performed when an operator powers-up the external defibrillator, and some are performed during operation of the defibrillator. FIG. 6 is not an exhaustive list of possible tests, nor is performance of any particular test listed in FIG. 6 essential to the invention. The tests and test groupings shown in FIG. 6 are merely an example illustrating this invention.

The first test grouping is the Battery Insertion Test or BIT. The BIT tests all internal subsystems, allows the user to verify PCMCIA card type, setup parameters, and the proper operation of systems that are only externally observable (e.g., LCD operation and button functionality). The BIT is performed whenever a good battery is inserted into the defibrillator, unless the defibrillator's electrodes are attached to a patient.

The second test grouping shown in FIG. 6 is the Monthly Periodic Self-Test (MPST). The MPST performs the same automated tests as the BIT, but in order to conserve power it does not run the externally observable systems (e.g., LCD, LED's, etc.). The MPST is performed once every 28 days so long as a good battery is maintained in the defibrillator.

The third test grouping shown in FIG. 6 is the Weekly Periodic Self-Test (WPST). The WPST performs essentially the same automated tests as the MPST, except the test shock is not performed in order to conserve power. The WPST is performed once every 7 days so long as a good battery is maintained in the defibrillator.

The fourth test grouping shown in FIG. 6 is the Daily Periodic Self-Test (DPST). The DPST performs fewer tests than the WPST in order to conserve power.

The fifth test grouping shown in FIG. 6 is the Power-On Self-Test (POST). The POST is performed whenever an operator turns the defibrillator from OFF to ON in preparation for use of the defibrillator on a patient. The tests performed in the POST are selected to provide the highest confidence of instrument functionality in the shortest possible time.

The final grouping of tests in FIG. 6 is the Runtime Tests. These tests are performed continually during runtime to

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assess the safety and effectiveness of portions of the defibrillator. The tests are explained in more detail below.

The self-tests listed in FIG. 6 are not necessarily listed in the order performed. The performance order depends in part on the interrelationship of the components and functions tested. To the extent there is no such relationship, then the self-test order is arbitrary.

In general, failure of a self-test results in an indication of an inoperable status or error status by the defibrillator's status indicator. For example, in the defibrillator described above, failure of a self-test would result in the display of the "Not OK" symbol by the system monitor and activation of the audible failure signal. The system monitor takes this action if it receives a signal from the CPU or from the system gate array that a test has failed (i.e., that a tested component is not functional or that the component's calibration could not be verified) or if the system monitor does not receive information showing that the currently-scheduled self-test has passed before the expiration of the watchdog's time-out period (e.g., 200 msec.).

In a preferred embodiment of this invention, self-test scheduling and result information may be stored in system memory for later diagnosis of the defibrillator by a technician or operator. For example, in the defibrillator described above, date and time information regarding the self-tests performed are stored in internal memory and/or in the removable memory 80 (e.g., PCMCIA card) so that a history of performed tests can be obtained by a technician or operator. In addition, if a self-test indicates that a component or subsystem is not functional or is out of calibration, or if any recalibration has been performed, detailed information about that test is stored in internal memory and/or in removable memory. Information regarding environmental conditions (temperature, humidity, moisture, impacts) may also be stored for use in later diagnosis.

The CPU self-test is a functional test. During the CPU self-test the CPU tests its internal register integrity and verifies its access to local and external memory locations. If the CPU does not pass these initial tests, it attempts to notify the user of a system failure by writing to a system failure register in the system monitor, resulting in a status display showing "Not OK". If the CPU does not respond to the system monitor within 200 msec of power on, the system monitor assumes the CPU is dead, and the "Not OK" symbol is displayed.

The System Gate Array self-test is also a functional test. In the System Gate Array self-test, the CPU verifies that it can write to and read from the system gate array register set. This test also tests other components of the system gate array, such as whether defibrillator waveform control state machines are functioning correctly. Test failures are handled as for the CPU self-test above.

The System Monitor Gate Array self-test is a functional test as well. The System Monitor Gate Array self-test verifies that the CPU can write to and read from the system monitor.

At the beginning of the Program ROM CRC (Cyclic Redundancy Check) self-test, the CPU resets the system monitor watchdog and executes a CRC on program ROM. This test is a functional test.

In the System RAM Checksum self-test (a functional test), RAM used for data memory is verified using a test pattern that has a high probability of identifying both address and data faults within RAM. Once the pattern has been written to system RAM, the test calculates a checksum based on the system RAM contents.

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In the Video RAM Checksum self-test, RAM used for video memory is verified in the same manner as for the system RAM. This self-test is a functional test.

In the Device Flash ROM Checksum self-test, a checksum of the voice data pointer and voice data record is calculated and compared with the checksum value stored in the internal flash ROM. This self-test is a functional test as well.

In the System Watchdog Verify self-test, the CPU verifies the watchdog by writing a known watchdog time-out into the watchdog register and looping until the watchdog time-out register in the system monitor indicates that the watchdog timer has expired. During this test, the watchdog outputs, NMI, and RESET are disabled. The CPU signals a failure if the watchdog timer does not expire within the expected time frame.

The PCMCIA Card Verify self-test is a functional test that checks for the presence and type of the removable memory.

The next four self-tests listed in FIG. 6—Front End Gain, Artifact System, CMR Channel, and Defibrillator Connector/Relay—are all part of the ECG front end tests. These tests verify the functionality and verify the calibration of the ECG input circuitry and the patient/electrode connection circuitry. These tests are not performed during the POST since the tests assume that there is no load attached to the defibrillator output connector.

An explanation of some special features of the external defibrillator of this invention is required as background for the ECG front end tests. FIG. 7 shows the ECG front end 35 in relationship to the system gate array 56, the high voltage delivery system 36, a test and isolation relay 76 and the patient connector 38, as well as communication channels among some of these elements. The test and isolation relay 76 is normally in the state shown in FIG. 7 so that no shock can be delivered from the high voltage delivery system 36 to the patient connector 38 and to the electrodes 40 attached to a patient.

In this state, any signals from electrodes 40 will pass through a pair of protective resistors 86 and 88 to an ECG amplifier 90. A high resolution A/D converter 92 digitizes the ECG data and sends it to the system gate array 56 for processing by the CPU to determine whether a shock is required. The system gate array 56 also sends control signals to the A/D converter 92.

The ECG front end 35 also has a patient/electrode connection tester consisting of a signal generator 94 connected to the ECG signal input lines through a pair of protection resistors. The signal generator 94 receives input from the ECG analog output and carrier frequency commands from the gate array. The patient/electrode connection tester also produces an artifact test signal which is sent through ECG amplifier 90 to the CPU via line 98. ECG signal collection and analysis and artifact detection are not part of the present invention.

During automated testing, the system gate array 56 uses the signal generator 94 as a test signal injector to verify the function of the various ECG front end elements, wiring to the patient connector 38, and the normally-open contacts of the test and isolation relay 76. To test the ECG processing elements, the system gate array 56 causes the signal generator 94 to inject a small, low-frequency signal mimicking the amplitude and frequency characteristics of an ECG signal, thereby simulating a patient being monitored by the defibrillator. As the frequency of this test signal is varied, the digital data stream from the system gate array is checked by the CPU for values indicative of proper gain and filtering

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characteristics of the ECG front end, thus verifying the functionality and calibration of the analog and A/D conversion pathways.

In the Defibrillator Connector/Relay self-test, the function of the test and isolation relay contacts 100 and 102 and patient connector wiring are tested. The system gate array 56 causes the signal generator 94 to emit a 100 microamp, 600 Hz test signal and concurrently switches the test and isolation relay 76 to the normally-open position (shown in phantom in FIG. 7). The test current signal is carried to a 4-wire connection 104 and 106 directly on the patient connector contacts, through the relay common connection, and into the high voltage delivery subsystem 36, where both signal lines are held at ground potential. The relay 76 is then switched to its normally closed position. Carrier voltage is measured in both positions is indicative of the resistance of the circuit tested. When the relay is in normally open position, the carrier voltage should be approximately equal to the full scale voltage of signal generator 94. When the relay is in the normally closed position, carrier voltage should be approximately zero.

Finally, in the Artifact System self-test, the system gate array causes the signal generator 94 to emit signals indicative of artifact generation at the electrodes. Proper receipt of artifact signals of the expected amplitude at the CPU verifies the function and calibration of this channel.

There are three battery-related self-tests that are members of each of the test groupings in the preferred embodiment. The battery tests described below are based on a defibrillator design using the battery capacity indicator described in U.S. patent application Ser. No. 08/182,605, now U.S. Pat. No. 5,483,165 filed Jan. 14, 1994, (specifically, the embodiment of FIG. 2) the disclosure of which application is incorporated herein by reference. Other battery charge sensor arrangements and other battery charge subsystem self-tests may be used, of course, without departing from the scope of the invention.

The Battery Sense Cell Measurement self-test listed in FIG. 6 refers to a battery capacity test described in Ser. No. 08/182,605 now U.S. Pat. No. 5,483,165 in which a parameter of a single battery cell is monitored to determine the remaining capacity of the entire battery. In the preferred defibrillator configuration, this functional self-test determines whether the remaining battery capacity is sufficient for performing one more use of the defibrillator by determining whether the voltage of the sense battery cell is above a threshold value of approximately 2 volts. If not, then a Low Battery Warning State is entered. If this state is entered during a BIT, DPST, WPST or MPST, the unit returns to Stand-by mode displaying the "Not OK" symbol. If this state is entered during a POST or during runtime, the user is alerted by a symbol appearing on the LCD display 83 and with an audible prompt.

The second listed battery self-test is the Battery Sense Cell Load Check. This calibration verification self-test verifies the sense cell additional load circuitry described in Ser. No. 08/182,605 now U.S. Pat. No. 5,483,165 by turning the additional load circuitry on and off and measuring the voltage load across the load resistor. This test can actually be performed while performing the first battery self-test.

The third listed battery self-test is the Battery Stack Check. This functional test measures the voltage of the entire battery cell stack as a cross-check against the Battery Sense Cell Measurement test. If a portion of the battery stack other than the sense cell has been damaged, the voltage of the entire stack could be different than that which would have been expected based on the sense cell test.

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In the Power Supplies Check calibration verification self-test, the system monitor activates the defibrillator's power supply system to supply power to all of the instrument's elements. Scaled representations of the voltages from the supplies are input for verification to the main CPU A/D converter. For example, the major power supplies are: +18 volt switched battery; +5 volt for system monitor; +5 volts for main logic and analog; -5 volt for analog only; -14 to -22 volt CPU adjustable for LCD bias; +20 volts for IGBT switch drives; +2.5 volt reference for ECG front end; +5 volt reference for main CPU A/D converter; and 50 ma current source supply for LCD backlight (tested by voltage developed). In addition, the high voltage supply is tested by its ability to charge the capacitor.

The HV Isolation Relay self-test determines the functionality of the test and isolation relay 76. In the first part of the test, the system gate array 56 moves the test and isolation relay to its normally open position, i.e., with the switches against contacts 100 and 102. The ECG front end measures the impedance across conductors 96 and 97. If the measured impedance corresponds to a predetermined impedance value, then the relay passes this part of the test.

The ECG front end then measures the impedance across conductors 96 and 97 with the test and isolation relay 76 in the normally closed position shown in FIG. 7. The measured impedance should be high (>14 k Ohms). If not, either a load is present at electrodes 40 or the relay failed to move completely to the normally closed position. In either case, the test fails, and the system monitor displays the "Not OK" symbol on the status indicator. In addition, failure to meet both parts of the Isolation Relay test prevents the defibrillator from performing the High Voltage Discharge Test described below.

Under normal conditions, the defibrillator used to implement and practice the preferred embodiment of this invention delivers a biphasic waveform to the patient, as described in more detail in U.S. patent application Ser. No. 08/227,553 now U.S. Pat. No. 5,607,454. FIG. 8 provides further information regarding the preferred defibrillator's high voltage delivery system and how its operation is verified and calibrated during self-test.

High voltage delivery system 36 has a capacitor or capacitor bank 112 which can be charged to a preset voltage through a high voltage charger 114 connected to the power supply system 46 and battery 32. Operation of the high voltage charger is controlled by system gate array 56. A high voltage switch 110 consisting of five switches A-E and a shunt resistor R_{BITE} controls delivery of the biphasic waveform from capacitor 112 to the patient connector 38 through test and isolation relay 76 under the control of system gate array 56.

Information regarding charge, current and voltage parameters at the capacitor is provided to system gate array 56 by a current and charge measurement device 116, an overvoltage detector 118 and a voltage divider 120. As described in more detail in Ser. No. 08/227,553 now U.S. Pat. No. 5,607,454, current and charge measurement device 116 is preferably a comparator that trips when a preset charge amount has been transferred from capacitor 112. The time required for this charge transfer is determined by system gate array 56 and is used to determine first and second phase durations via a look-up table in system gate array 56. All information and control signals pass among the elements via communication channels, some of which are shown schematically in FIG. 8.

As explained in Ser. No. 08/227,553 now U.S. Pat. No. 5,607,454, resistor R_{BITE} is part of an overcurrent protection

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mechanism to protect circuit components from the effects of high current in the event that the impedance load between electrodes 40 is too low. Unless the initial current as measured by current and charge measurement device 116 is below a preset threshold, R_{BITE} is kept in the waveform delivery circuit to limit the current flowing from capacitor 112 through the switching mechanism 110.

The high voltage delivery system has an overvoltage protector that protects switching circuit components from the effects of excessive voltage in the event of a higher than expected patient load resistance by preventing any transition from a first biphasic waveform phase to a second biphasic waveform phase. Analog voltage information from the capacitor is fed from a voltage divider 122 to an overvoltage detector 118. Overvoltage detector 118 is preferably a comparator that trips at a preset voltage. The status of the comparator is communicated to system gate array 56, which controls operation of the switching mechanism 110.

Finally, analog information regarding the charge state of capacitor 112 is sent to CPU 34 via voltage divider 120, where it is converted to digital form. This capacitor voltage information is used by the CPU to control capacitor charging.

The High Voltage Delivery Subsystem self-test actually includes a number of individual self-tests. Capacitor 112 is charged to full voltage (e.g., approx. 1710 volts). As the capacitor voltage rises, the calibration of the overvoltage detector 118 is checked to see that it trips at the proper threshold voltage. If it fails to trip, the system gate array returns a signal to the system monitor to show "Not OK" on the status indicator.

After the capacitor has been fully charged, the system gate array 56 sets the high voltage switch 110 to its normal initial discharge position (switches A and E closed, all other switches open) and commences discharge of the capacitor through the test and isolation relay 76 to the test load resistance R_L . R_L simulates the load of a patient to whom the defibrillators electrodes may be attached. R_L is preferably approximately 10 ohms, however, which is smaller than the minimum allowable patient resistance for the defibrillator. This low resistance assures that the test stresses all of the elements tested in the high current pathways for worst-case patient conditions.

During this part of the High Voltage Delivery self-test, the system gate array verifies overcurrent detection calibration by determining whether the CPU correctly identifies the overcurrent condition detected by current and charge measurement device 116. The system gate array also checks for proper operation of the charge threshold detector and that the overvoltage detector 118 trips properly when the capacitor voltage drops below the safe voltage threshold, in both cases by determining whether these events occur at their expected times. If either of these parameters is not its expected value, the system monitor displays "Not OK" on the status indicator.

As the capacitor voltage drops during discharge through the test load, the current measured by the current and charge measurement device 116 drops as well. The CPU marks the time the current drops below the overcurrent threshold (t_0). As the current continues to fall, the CPU marks the time (t_1) that the current reaches a value that is 37% of the overcurrent threshold. The difference of these two times is the time constant given by the product of the capacitor value C and the series resistance:

$$t_1 - t_0 = (R_L + R_{BITE}) \cdot C$$

Switch D is then closed to short out R_{BITE} . This results in another overcurrent situation, and the CPU once again

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marks the time (t_2) of capacitor decay to the overcurrent threshold and the time (t_3) to 37% of the threshold. Since R_{BITE} has been removed,

$$t_3 - t_2 = R_L \cdot C$$

Since the time measurements can be made very accurately, the relationships between the resistive and capacitive components (and therefore their calibration) can be verified very accurately as well:

$$\frac{t_1 - t_0}{t_3 - t_2} = \frac{R_L + R_{BITE}}{R_L}$$

$$C = \frac{t_1 - t_2}{R_L}$$

If the calculated resistance value differs from the expected value by more than a predetermined amount (e.g., 1%), or if the calculated capacitance value differs from the expected value by more than a predetermined amount (e.g., 5%), the system monitor displays the "Not OK" symbol.

In the preferred embodiment, the gain of the comparators of the current and charge measurement subsystems are determined by the particular values of the components used during assembly of the device. Due to allowable tolerance variation of the components, the times that the currents pass associated threshold values (t_0 and t_2) may vary from ideal values ($t_0(\text{ideal})$ and $t_2(\text{ideal})$). Actual values of t_0 and t_2 are measured during self-test of the instrument and compared to stored $t_0(\text{ideal})$ and $t_2(\text{ideal})$. If the actual values of t_0 and t_2 measured during the High Voltage Discharge Test differ from the ideal values by less than a preset amount, then the gain on the comparator of the current and charge measurement device 116 is automatically recalibrated by the CPU to a range closer to the ideal value. If the actual values differ from the ideal by the preset amount or more, the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

In a similar manner, the expected time for times for the measured charge delivery to cross the charge threshold used to determine first and second phase durations in normal operation is compared to the actual time. If the difference is less than a preset value, the CPU recalibrates the phase durations by recalculating the phase duration values according to a predetermined equation and storing the new values in the look-up table. Alternatively, the CPU could simply replace the original look-up table with another that is correlated with a particular time difference. If the time difference is equal to or greater than the preset value, then the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

Another feature of the external defibrillator of preferred embodiment is an undercurrent detector. If the patient to whom the electrodes are attached has an impedance greater than a specified value, or if one of the electrodes has become dislodged or unattached, in normal operation the defibrillator's discharge will abort. This condition is detected by the current and charge measurement device 116 in conjunction with the CPU.

The High Voltage Delivery self-test verifies calibration of the undercurrent detector by determining whether the low current condition is detected as the capacitor continues its discharge and the discharge current falls. If the CPU fails to detect the undercurrent condition, the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

After the capacitor has completely discharged, it is recharged and discharged through the second current path by

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opening all switches in high voltage switch 110, then closing switches B and C. Many of the same parameters described above can be measured to verify the functionality of switches B and C.

The Waveform Delivery self-test is performed only while the defibrillator is operating in normal mode (e.g., connected to a patient). The defibrillator evaluates the measured and calculated waveform parameters after each delivered shock to determine if the waveform was delivered as expected. For example, if the defibrillator is constructed and operated according to U.S. patent application Ser. No. 08/227,553 now U.S. Pat. No. 5,607,454, the defibrillator will analyze waveform parameters such as start voltage, phase 2 end voltage, phase 1 duration and phase 2 duration. If the delivered waveform parameters cannot be reconciled with other information available to the defibrillator, the defibrillator warns the operator of a potential fault condition by, e.g., displaying a warning on the defibrillator's LCD.

The three Calibration Standard self-tests are an automatic way of verifying that defibrillator system standards have not drifted out of calibration. The standards are the values of R_L , R_{MTR} , the system monitor clock, the CPU clock, the CPU A/D converter reference voltage and the ECG front end A/D converter reference voltage. For all test groupings except the run time test, the voltage references are checked against each other to determine if either has drifted far enough from its expected value to affect the accuracy of the defibrillator. Specifically, the analog reference voltage for the ECG front end A/D converter (which has an expected value of 2.5 volts in the preferred embodiment) is measured by the CPU A/D converter. If the measured digital value differs from 2.5 volts by more than a predetermined tolerance, then at least one of the two reference voltages (i.e., either the ECG front end A/D converter reference voltage or the CPU A/D converter reference voltage) has drifted so far so as to affect the reliability of the device.

The time references are cross-checked in a similar way. The CPU counts the clock pulses from the system monitor clock for a predetermined amount of time (as measured by the CPU clock). If the number of counted system monitor clock pulses differs from its expected value by more than a predetermined amount, then at least one of the two clocks has drifted out of the tolerance range.

In addition, as discussed above, the High Voltage Delivery self-test cross-checks the values of R_L and R_{MTR} . Verification of the calibration of all three sets of reference variables is a prerequisite to the overcurrent detection calibration and charge threshold detection calibration described above.

In normal stand-by mode, the contacts beneath all buttons should be open. The Stuck Button self-test determines whether any of the contacts are closed. If so, the test returns a "Not OK" signal.

The remaining tests require user intervention and/or observation and are therefore part of only the BFI or POST test groupings. In the Button test, the user is prompted to depress identified buttons on the instrument to determine whether the buttons are functioning properly. All of the other tests run without user intervention. They each require the user to observe that the defibrillator elements tested are functioning correctly.

In addition to performing the self-tests according to the periodic schedule and in response to the battery insertion and operation of the defibrillator (as shown in FIG. 6), a group of self-tests can be performed automatically in response to environmental events, such as mechanical shock, e.g. as in a fall (as measured by an accelerometer); vibration (also as measured by an accelerometer); the inva-

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sion of moisture into the defibrillator housing (as measured by a humidity sensor); or exposure of the defibrillator to temperature extremes (as measured by a thermocouple, thermistor or other temperature sensor).

Variations of the structure and methods described above are within the scope of this invention. Tests and test structures may be tailored to meet the needs of a particular defibrillator design and its intended use environment.

What is claimed is:

1. An external defibrillator comprising:
 - a high voltage delivery system comprising an energy source, an electrode interface and a switch connecting the energy source to the electrode interface;
 - a controller operably connected to the high voltage delivery system; and
 - a self-test system comprising a defibrillator status indicator, a test signal generator, and means for operating the defibrillator status indicator and the test signal generator prior to any attempted use of the defibrillator.
2. The defibrillator of claim 1 wherein the self-test system further comprises a functionality tester and communication channels between the functionality tester and the test signal generator and between the functionality tester and the status indicator.
3. The defibrillator of claim 2 wherein the self-test system further comprises a communication channel between the functionality tester and the switch.
4. The defibrillator of claim 2 wherein the self-test system further comprising a communication channel between the functionality tester and the controller.
5. The defibrillator of claim 2 wherein the self-test system further comprises a relay having an operational position and a test position, the self-test system further comprising a communication channel between the functionality tester and the relay.
6. The defibrillator of claim 1 wherein the self-test system further comprises a calibration verifier and communication channels between the calibration verifier and the test signal generator and between the calibration verifier and the status indicator.
7. The defibrillator of claim 6 further comprising an overcurrent detector, the self-test system further comprising a communication channel between the calibration verifier and the overcurrent detector.
8. The defibrillator of claim 6 further comprising an undercurrent detector, the self-test system further comprising a communication channel between the calibration verifier and the undercurrent detector.
9. The defibrillator of claim 6 further comprising an overvoltage detector, the self-test system further comprising a communication channel between the calibration verifier and the overvoltage detector.
10. The defibrillator of claim 6 further comprising an ECG front end, the self-test system further comprising a communication channel between the calibration verifier and the ECG front end.
11. The defibrillator of claim 6 wherein the high voltage delivery system comprises a resistor, the self-test system further comprising a communication channel between the calibration verifier and the resistor.
12. The defibrillator of claim 11 wherein the controller comprises means for using the high voltage delivery system resistor as a reference standard for the defibrillator.
13. The defibrillator of claim 11 further comprising a second resistor in communication with the controller, wherein the controller comprises means for using the high voltage delivery system resistor and the second resistor together as reference standards for the defibrillator.

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14. The defibrillator of claim 6 wherein the high voltage delivery system comprises a capacitor, the self-test system further comprising a communication channel between the calibration verifier and the capacitor.

15. The defibrillator of claim 6 wherein the controller comprises a clock, the self-test system further comprising a communication channel between the calibration verifier and the clock.

16. The defibrillator of claim 15 wherein the controller comprises means for using the controller clock as a reference standard for the defibrillator.

17. The defibrillator of claim 16 further comprising a second clock in communication with the controller, wherein the controller comprises means for using the controller clock and the second clock together as reference standards for the defibrillator.

18. The defibrillator of claim 6 further comprising a reference voltage source, the self-test system further comprising a communication channel between the calibration verifier and the voltage source.

19. The defibrillator of claim 18 wherein the controller comprises means for using the reference voltage source as a reference standard for the defibrillator.

20. The defibrillator of claim 19 further comprising a second voltage source in communication with the controller, wherein the controller comprises means for using the first and second voltage sources together as reference standards for the defibrillator.

21. The defibrillator of claim 1 further comprising a battery, the self-test system further comprising a battery condition tester and communication channels between the battery condition tester and the battery, between the battery condition tester and the status indicator, and between the battery condition tester and the test signal generator.

22. The defibrillator of claim 1 wherein the test signal generator comprises a system monitor.

23. The defibrillator of claim 22 wherein the system monitor comprises an application specific integrated circuit.

24. The defibrillator of claim 22 further comprising a controller power supply, wherein the system monitor comprises a system monitor power supply separate from the controller power supply.

25. The defibrillator of claim 22 wherein the system monitor further comprises means for generating periodic test signals.

26. The defibrillator of claim 22 wherein the system monitor further comprises means for generating test signals in response to specified events or conditions.

27. The defibrillator of claim 26 further comprising means for receiving a removable battery and for connecting a battery to the high voltage delivery system, in which the event or condition is the insertion of a battery into the defibrillator.

28. The defibrillator of claim 22 in which the event or condition is environmental.

29. The defibrillator of claim 28 in which the environmental event or condition is temperature.

30. The defibrillator of claim 28 in which the environmental event or condition is moisture.

31. The defibrillator of claim 28 in which the environmental event or condition is mechanical shock.

32. The defibrillator of claim 28 which the environmental event or condition is vibration.

33. The defibrillator of claim 22 wherein the system monitor comprises a watchdog timer.

34. The defibrillator of claim 1 wherein the status indicator comprises a sound generator.

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35. The defibrillator of claim 1 further comprising memory and a communication channel between the self-test system and the memory.

36. The defibrillator of claim 1 wherein the status indicator comprises a visual display.

37. The defibrillator of claim 36 in which the visual display comprises means for providing fail-safe operation.

38. A defibrillator comprising:

a high voltage delivery system comprising an energy source and a switch connecting the energy source to the exterior of the defibrillator;

a controller operably connected to the high voltage delivery system; and

a self-test system comprising a defibrillator status indicator, a test signal generator, and a recalibrator.

39. The defibrillator of claim 38 further comprising a current sensor, the self-test system further comprising a communication channel between the recalibrator and the current sensor.

40. The defibrillator of claim 38 further comprising a waveform shape controller, the self-test system further comprising a communication channel between the recalibrator and the waveform shape controller.

41. An external defibrillator comprising:

a high voltage delivery system comprising an energy source, an electrode interface and a switch connecting the energy source to the electrode interface;

a controller operably connected to the high voltage delivery system; and

a self-test system comprising a defibrillator status indicator, a periodic test signal generator, and means for operating the defibrillator status indicator and the periodic test signal generator prior to any attempted use of the defibrillator.

42. A method for automatically determining and indicating an operational status of an external defibrillator, the method comprising the following steps:

generating a test signal within the external defibrillator automatically and periodically;

performing a self-test in response to the test signal; and indicating the operational status of the defibrillator based on a result of the self-test;

the generating, performing and indicating steps being performed prior to any attempted use of the defibrillator.

43. An external defibrillator comprising:

a high-voltage delivery system; and

a self-test system, the self-test system comprising a test signal generator and a fail-safe visual display.

44. A method for automatically determining and indicating an operational status of an external defibrillator, the method comprising the following steps:

generating a test signal within the external defibrillator automatically in response to a predetermined event or condition;

performing a self-test in response to the test signal; and indicating the operational status of the defibrillator based on a result of the self-test;

the generating, performing and indicating steps being performed prior to any attempted use of the defibrillator.

45. The method of claim 44 wherein the step of generating a test signal within the defibrillator automatically in response to a predetermined event or condition comprises

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generating a test signal within the defibrillator automatically in response to insertion of a battery into the defibrillator.

46. The defibrillator of claim 44 in which the step of generating a test signal within the defibrillator automatically in response to a predetermined event or condition comprises generating a test signal within the defibrillator automatically in response to an environmental event or condition.

47. The method of claim 46 in which the step of generating a test signal within the defibrillator automatically in response to an environmental event or condition comprises generating a test signal within the defibrillator automatically in response to temperature.

48. The method of claim 46 in which the step of generating a test signal within the defibrillator automatically in response to an environmental event or condition comprises generating a test signal within the defibrillator automatically in response to moisture.

49. The method of claim 46 in which the step of generating a test signal within the defibrillator automatically in response to an environmental event or condition comprises generating a test signal within the defibrillator automatically in response to mechanical shock.

50. The method of claim 46 in which the step of generating a test signal within the defibrillator automatically in response to an environmental event or condition comprises generating a test signal within the defibrillator automatically in response to vibration.

51. The method of claim 44 wherein the step of performing a self-test comprises determining functionality of a defibrillator component or system.

52. The method of claim 44 wherein the step of performing a self-test comprises verifying calibration of a defibrillator component or system.

53. The method of claim 52 wherein the step of performing a self-test comprises performing a calibration verification self-test, the method further comprising the step of recalibrating a defibrillator component or system in response to the calibration verification self-test.

54. The method of claim 52 wherein the step of performing a self-test comprises discharging a capacitor and measuring electrical and time values associated with the capacitor's discharge.

55. The method of claim 52 wherein the step of performing a self-test comprises using a resistance within the defibrillator as a reference value.

56. The method of claim 52 wherein the step of performing a self-test comprises using two resistances within the defibrillator as reference values through a comparison of two resistance values.

57. The method of claim 52 wherein the step of performing a self-test comprises using a voltage source within the defibrillator as a reference value.

58. The method of claim 52 wherein the step of performing a self-test comprises using two voltage sources within the defibrillator as reference values through a comparison of two voltage source values.

59. The method of claim 52 wherein the step of performing a self-test comprises using a clock within the defibrillator as a reference value.

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60. The method of claim 52 wherein the step of performing a self-test comprises using two clocks within the defibrillator as reference values through a comparison of two clocks.

61. The method of claim 44 wherein the indicating step comprises displaying status information on a visual display.

62. The method of claim 61 wherein the displaying step comprises providing an active display signal to the visual display, the visual display having a first state when provided with the active display signal and a second state when not provided with the active display signal, the second state indicating a nonoperational state of the defibrillator.

63. The method of claim 62 wherein the step of providing an active display signal comprises providing an AC signal.

64. The method of claim 44 wherein the indicating step comprises providing audible status information.

65. The method of claim 44 wherein the step of generating a test signal within the defibrillator automatically in response to a predetermined event or condition comprises generating a test signal within the defibrillator automatically in response to the passage of time.

66. The method of claim 44 wherein the step of performing a self-test comprises recalibrating a defibrillator component or system.

67. A method for testing and indicating an operational status of an external defibrillator comprising the following steps:

generating a test signal within the external defibrillator automatically and periodically;

performing a plurality of self-tests in response to the test signal to determine the operational status of a plurality of components of the defibrillator, the tests being performed without human intervention prior to any attempted use of the defibrillator; and

indicating the operational status of the defibrillator in response to at least one of the self-tests.

68. The method of claim 67 wherein the generating step comprises generating a test signal within the defibrillator automatically on a predetermined schedule.

69. The method of claim 67 further comprising the step of generating a test signal within the defibrillator automatically in response to a predetermined event.

70. The method of claim 69 further comprising the step of generating a test signal within the defibrillator automatically in response to an environmental condition or event.

71. The method of claim 67 wherein the step of performing a plurality of self-tests comprises determining functionality of a defibrillator component or system.

72. The method of claim 71 wherein the step of performing a plurality of self-tests comprises verifying calibration of a defibrillator component or system.

73. The method of claim 72 further comprising the step of automatically recalibrating a defibrillator component or system in response to a self-test.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,879,374
DATED : March 9, 1999
INVENTOR(S) : Powers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, (line 9), after "abandoned" insert --,--.

Column 10, (line 38), delete "553now" and insert therefor --553 now--.

Column 10, (line 39), after "preferred" insert --external--.

Column 10, (line 67), delete "5,697,454" and insert therefor --5,607,454--.

IN THE CLAIMS

Column 15, (line 54), delete "22" and insert therefor --26--.

Signed and Sealed this
Seventeenth Day of August, 1999

Attest:



Q. TODD DICKINSON

Attesting Officer

Acting Commissioner of Patents and Trademarks

Exhibit C





US005800460A

United States Patent [19]

Powers et al.

[11] Patent Number: 5,800,460

[45] Date of Patent: Sep. 1, 1998

[54] **METHOD FOR PERFORMING SELF-TEST
IN A DEFIBRILLATOR**

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B. Morgan, Bainbridge Island, all of
Wash.

[73] Assignee: Heartstream, Inc., Seattle, Wash.

[21] Appl. No.: 834,346

[22] Filed: Apr. 16, 1997

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Product Brochure from "Vivalink AED Automatic External Defibrillator System" by Survivalink Corporation, 2975 84th Lane NE, Minneapolis, MN 55449 (4 pages total).

Primary Examiner—William E. Kamm

Attorney, Agent, or Firm—James R. Shay; Cecily Anne Snyder

Related U.S. Application Data

[60] Continuation of Ser. No. 468,196, Jun. 6, 1995, abandoned, which is a division of Ser. No. 240,272, May 10, 1994, which is a continuation-in-part of Ser. No. 63,631, May 18, 1993, abandoned.

[51] Int. Cl.⁶ A61N 1/39

[52] U.S. Cl. 607/5

[58] Field of Search 607/4-8; 364/481

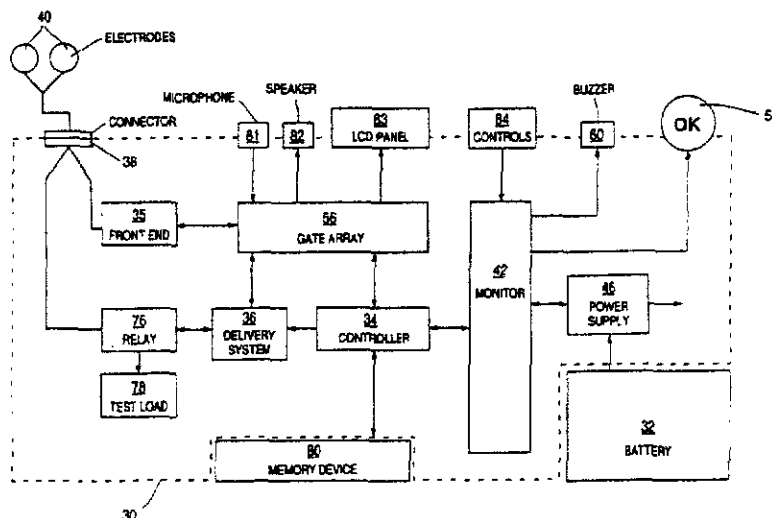
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[57] **ABSTRACT**

A defibrillator with an automatic self-test system that includes a test signal generator and a defibrillator status indicator. The test system preferably performs functional tests and calibration verification tests automatically in response to test signals generated periodically and/or in response to predetermined conditions or events and indicates the test results visually and audibly. The invention also relates to a method for automatically determining and indicating a defibrillator's status without human intervention.

7 Claims, 7 Drawing Sheets



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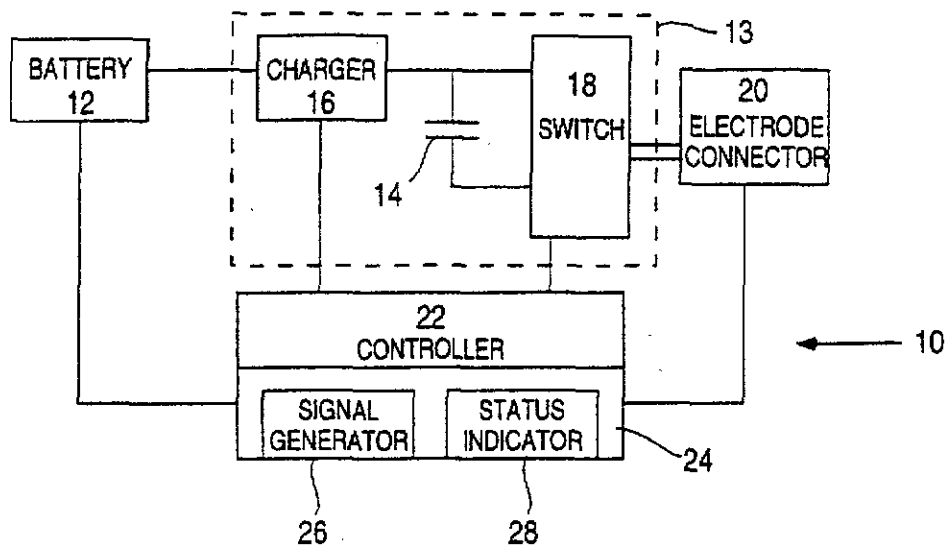


FIG. 1

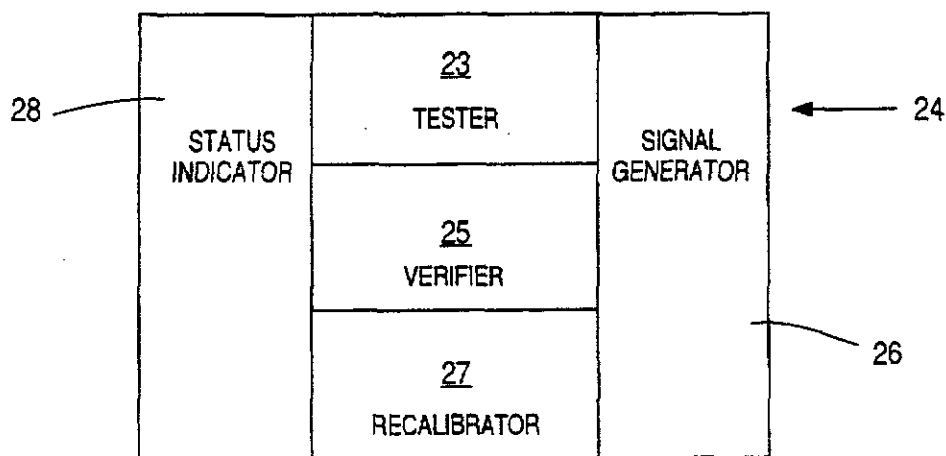


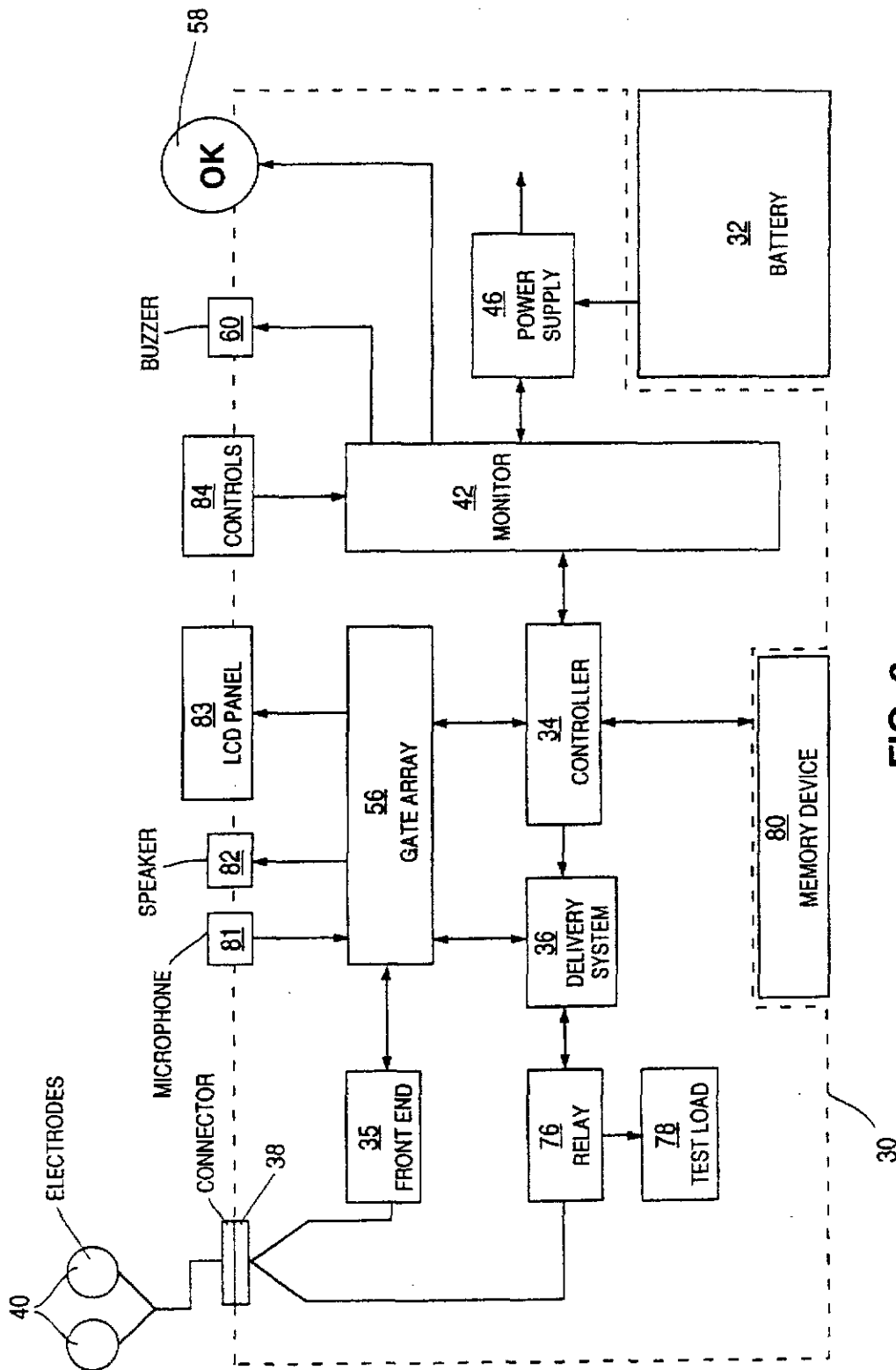
FIG. 2

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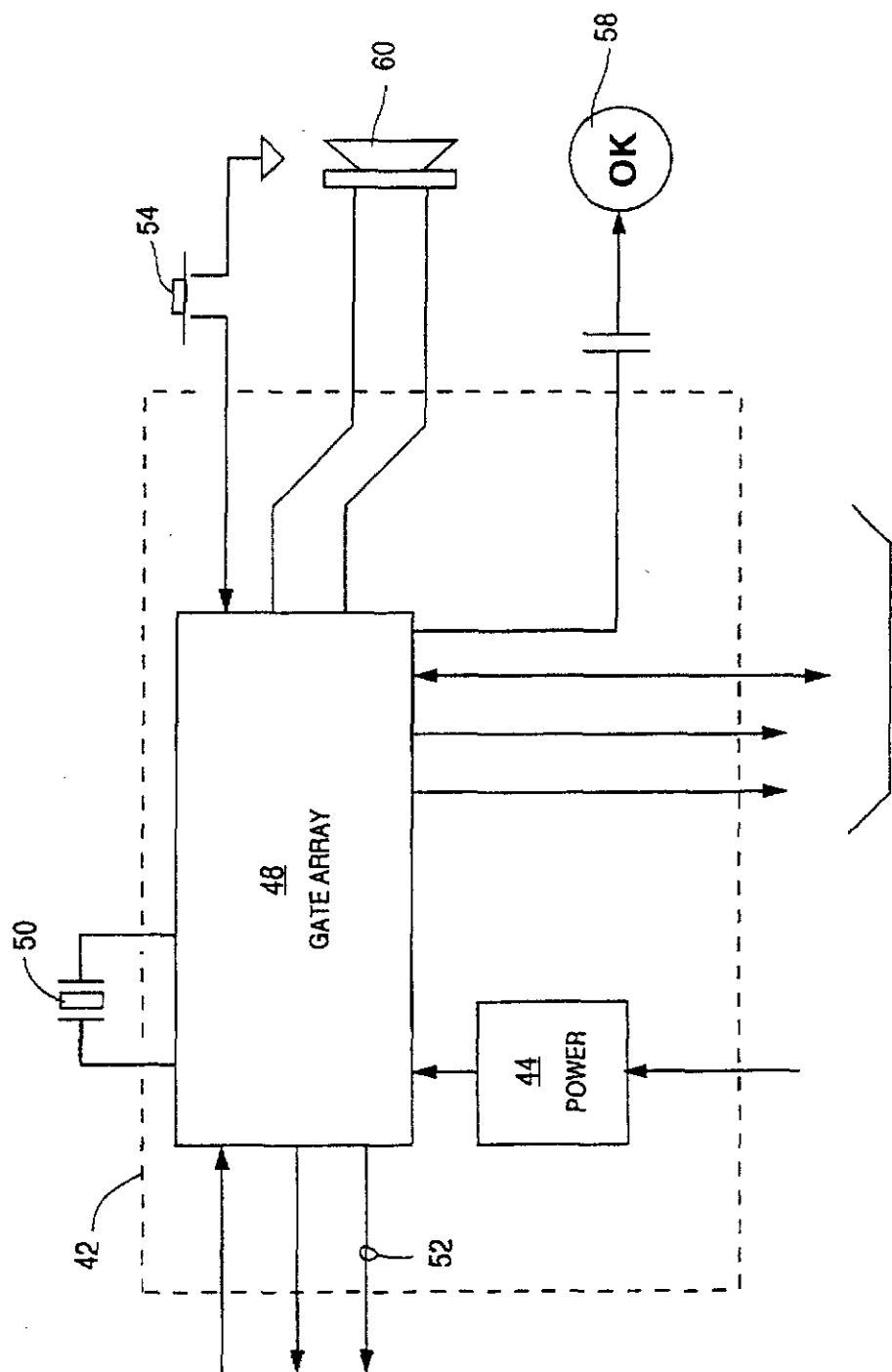


FIG. 4

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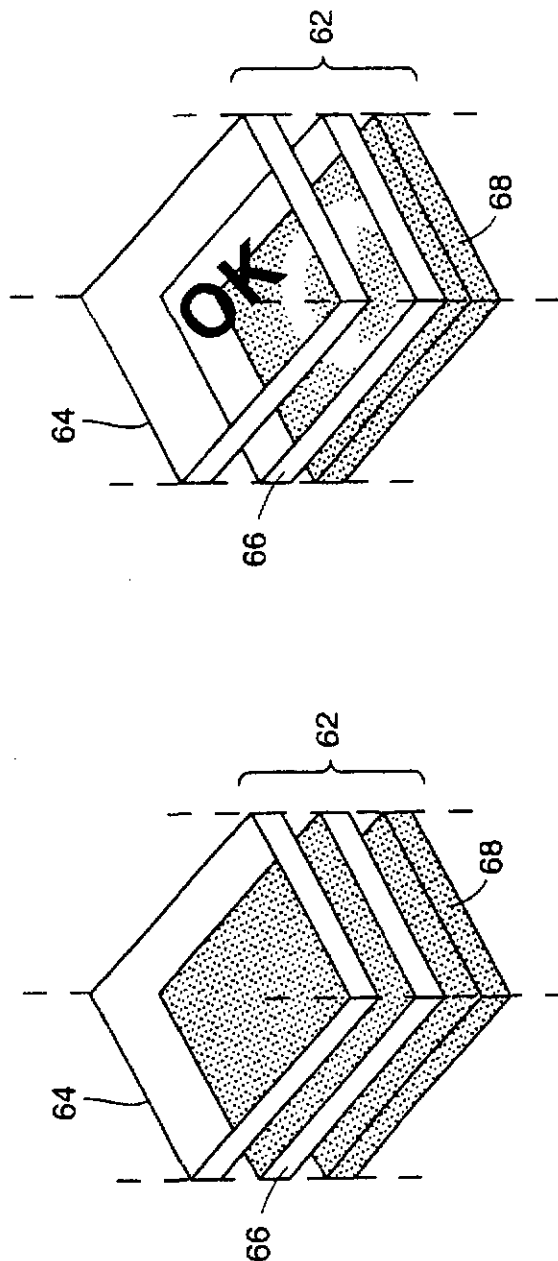


FIG. 5b

FIG. 5a

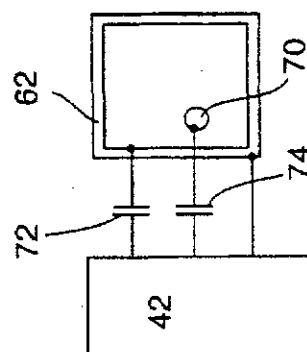


FIG. 5e

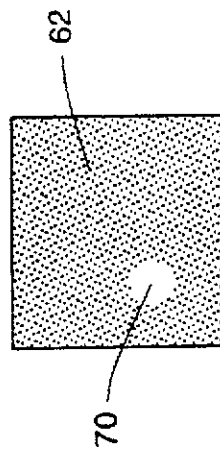


FIG. 5d

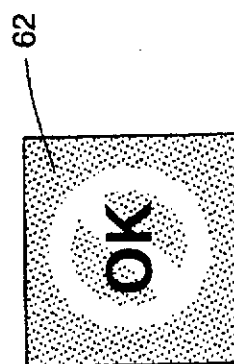


FIG. 5c

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TEST DESCRIPTION	BIT	WPST	MPST	DPST	POST	RUN TIME
CPU SELF-TEST	X	X	X	X	X	
SYSTEM GATE ARRAY	X	X	X	X	X	
SYSTEM MONITOR GATE ARRAY	X	X	X	X	X	
PROGRAM ROM CRC	X	X	X	X	X	
SYSTEM RAM CHECKSUM	X	X	X	X	X	
VIDEO RAM CHECKSUM	X	X	X			
DEVICE FLASH ROM CHECKSUM	X	X	X			
SYSTEM WATCH DOG	X	X	X	X	X	X
PCMCIA CARD VERIFY	X					
FRONT END GAIN	X	X	X	X		
ARTIFACT SYSTEM	X	X	X	X		
CMR CHANNEL	X	X	X	X		
DEFIBRILLATOR CONN/RELAY	X	X	X	X		
BATTERY SENSE CELL MEASUREMENT						
BATTERY SENSE CELL LOAD MEASUREMENT	X	X	X	X	X	X
BATTERY STACK LOAD CHECK	X	X	X	X	X	X
POWER SUPPLIES CHECK	X	X	X	X	X	X
HV ISOLATION RELAY	X	X	X			
HIGH VOLTAGE DELIVERY SUBSYSTEM	X	X	X			
WAVEFORM DELIVERY						X
CALIBRATION STD. VOLTAGE	X	X	X	X	X	X
CALIBRATION STD. TIME	X	X	X	X	X	X
CALIBRATION STD. RESISTANCE	X	X	X			
STUCK BUTTON TEST	X	X	X	X		
BUTTON TEST	X					
LIGHT ALL LED'S	X				X	
LCD TEST PATTERN	X					
LCD BACKLIGHT VERIFY	X					
SPEAKER OUTPUT TEST	X				X	
PIEZO BEEPER TEST	X				X	

FIG. 6

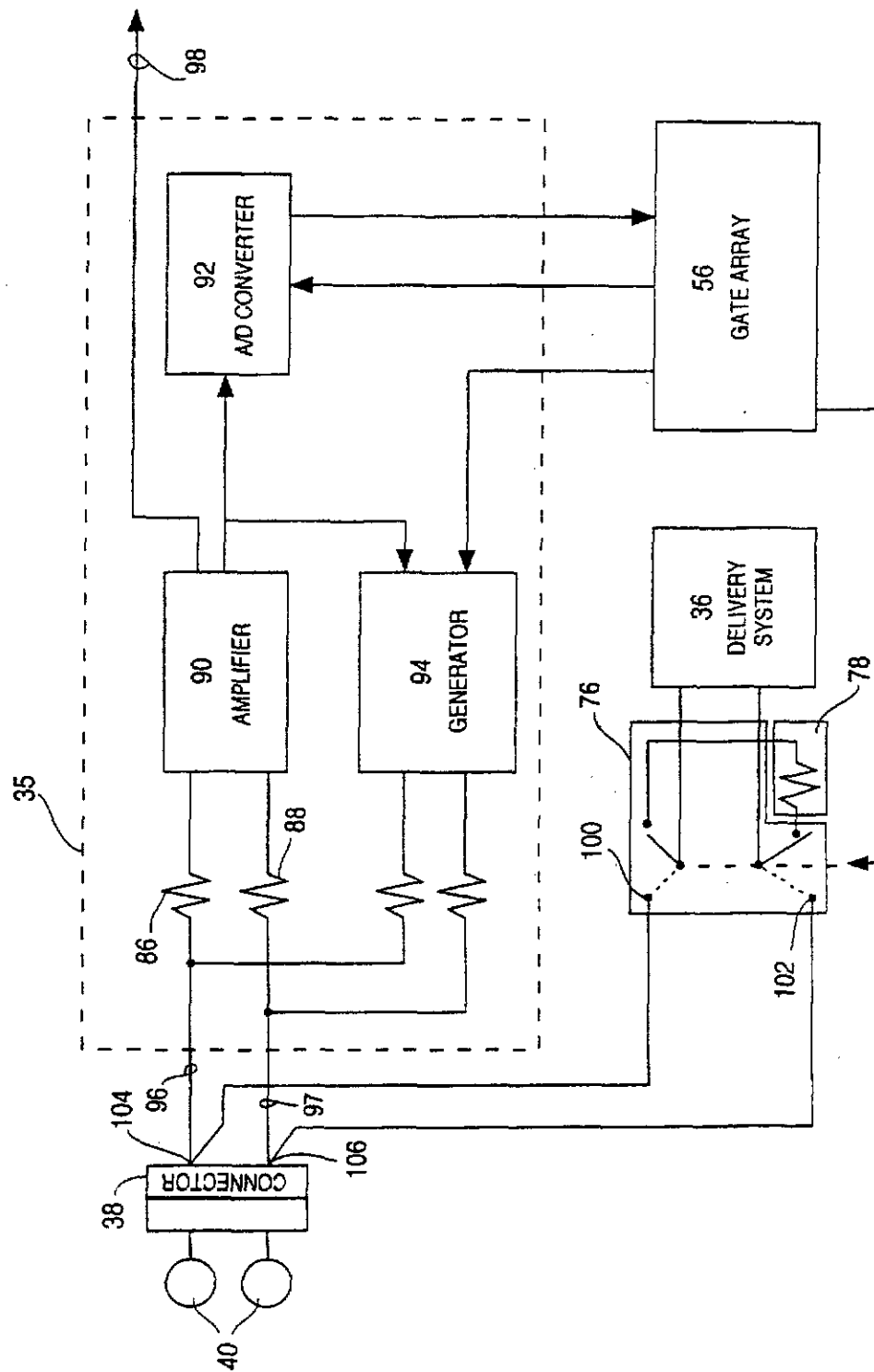


FIG. 7

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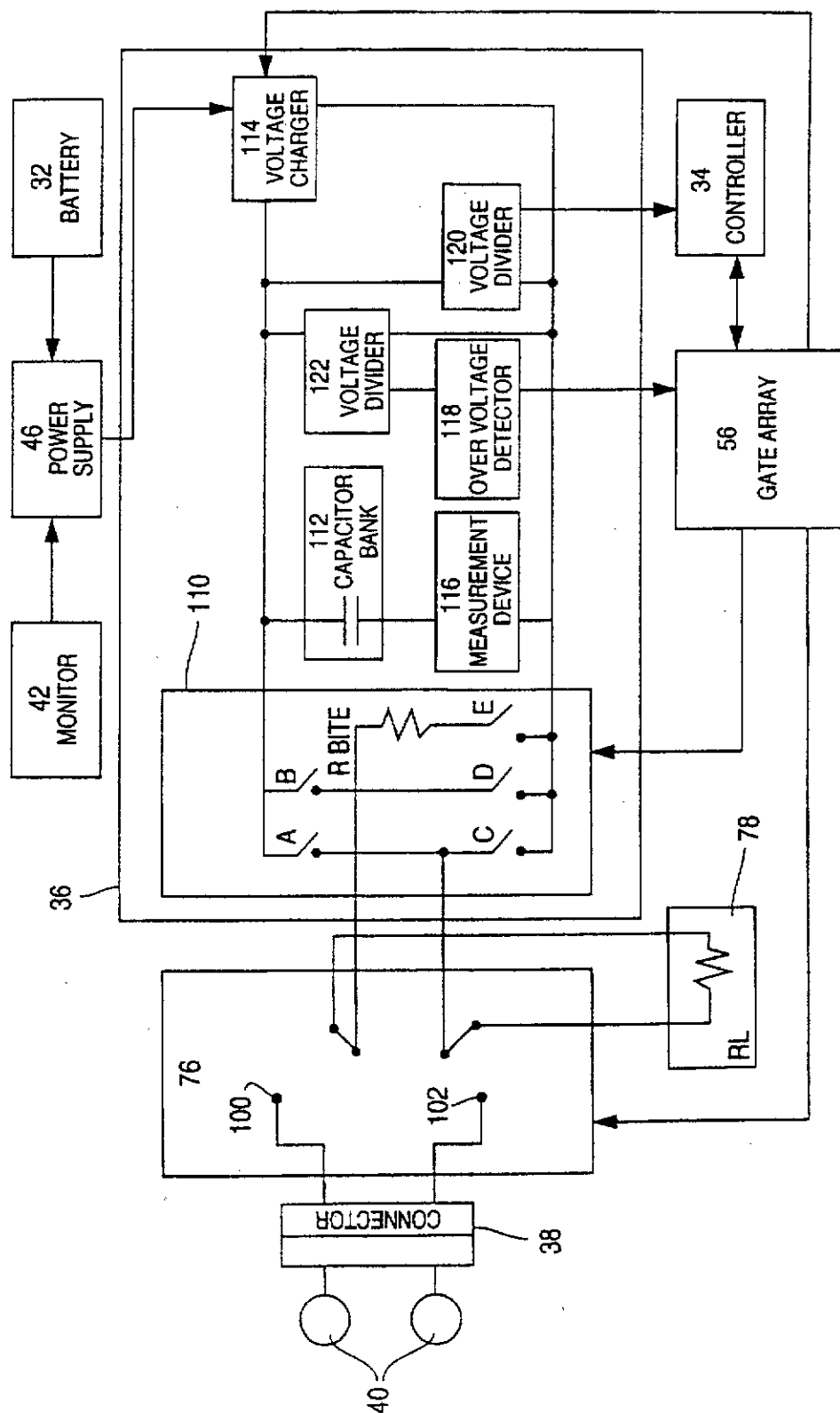


FIG. 8

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METHOD FOR PERFORMING SELF-TEST IN A DEFIBRILLATOR

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 08/468,196, filed 6 Jun., 1995, now abandoned, which is a divisional of U.S. patent application Ser. No. 08/240,272, filed May 10, 1994, which is a continuation-in-part of U.S. patent application Ser. No. 08/063,631, filed May 18, 1993, and now abandoned the disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates generally to a defibrillator system that performs periodic self-tests and, in particular, to a method and apparatus for performing periodic functional, calibration and safety tests in an automatic external defibrillator to verify that the defibrillator's components and operation are within preset specifications.

Prior art external defibrillators were used primarily in the hospital. In that environment, the frequency with which a particular defibrillator was used was relatively high, e.g., on the order of several times per week. Periodic verification tests for these prior art defibrillators typically amounted to a battery level test and a functional test in which the defibrillator was hooked to a test load and discharged. These tests were usually performed once per day or once per shift per manufacturer recommendations. Other tests, such as recalibration of internal circuit components by a biomedical technician, were performed less often, on the order of twice per year, also pursuant to manufacturer recommendations. Each of these maintenance tests for prior art defibrillators was initiated and performed by human operators.

SUMMARY OF THE INVENTION

While adequate for relatively frequently-used hospital-based defibrillators, prior art defibrillator test apparatuses and procedures are not optimal for use with portable defibrillators that are used less frequently. For example, defibrillators carried by emergency medical vehicles might need to be used only on a monthly basis. The burden of performing manual battery and performance tests on a daily basis could outweigh the benefits of carrying the infrequently-used defibrillator on the vehicle. The tests should therefore be performed by the defibrillator automatically.

Because the tests are performed automatically, the tests should be both accurate and reliable. The portable defibrillator's mobile environment could add to the frequency of defibrillator component failure, thus increasing the need for periodic tests. In addition, portable defibrillators could be exposed to environmental conditions (such as severe vibration, sudden impacts, heat or moisture) that require an immediate reevaluation of a defibrillator's operational status.

Also, the nature of the tests performed should be different in the portable defibrillator environment because of the relatively infrequent use of the defibrillators. Deterioration of system components over time could move the defibrillator out of its originally specified operating parameters. An infrequently used defibrillator should provide an operator with an indication not only of whether it will operate at all but also verify that the defibrillator meets its established specifications.

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Defibrillators are used in emergency situations in which time is of the essence. The operational status of a particular defibrillator as determined by the self-tests should be therefore readily apparent to an operator.

This invention is an external defibrillator that generates a test signal automatically in response to a predetermined schedule, in response to a predetermined event or condition, or periodically. The self-test system preferably turns on a power system within the external defibrillator in response to the test signal and performs a first test on a first periodic schedule and a second test on a second periodic schedule.

The invention is described in more detail below with respect to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram showing a defibrillator according to this invention.

FIG. 2 is a schematic diagram showing a testing system of a defibrillator according to this invention.

FIG. 3 is a block diagram showing some of the components of an external defibrillator according to a preferred embodiment of this invention.

FIG. 4 is a block diagram showing the system monitor of the embodiment of FIG. 3.

FIG. 5 parts (a)-(e) show various aspects of a visual display according to the embodiment of FIG. 3.

FIG. 6 is a table showing groupings of external defibrillator self-tests according to a preferred embodiment of this invention.

FIG. 7 is a block diagram showing the interaction of an ECG front end and a testing system according to a preferred embodiment of this invention.

FIG. 8 is a block diagram showing the interaction of a high voltage delivery system and a testing system according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

This invention is a method and apparatus for automatically determining the status of a defibrillator, for displaying that status to a user or operator, and, for recalibrating certain defibrillator components. The invention is particularly useful for increasing the reliability of infrequently-used defibrillators by providing an indication of a defibrillator's operational status and by recalibrating the defibrillator, where possible, prior to any attempted use of the defibrillator.

In a preferred embodiment, the defibrillator automatically generates a test signal either (1) periodically in response to the passage of time or (2) in response to a specified event or condition, such as the insertion of a new battery or a manual power-up command from an operator. The test signal initiates a plurality of preset self-tests within the defibrillator. The self-tests may include functional tests that verify the operation of certain defibrillator components and subsystems. The self-tests may also include calibration verification tests that determine whether certain defibrillator components and subsystems are operating at preset specifications or within preset specification ranges. In addition, the defibrillator may automatically recalibrate certain components or subsystems in response to a calibration verification test.

No matter what test or collection of automatic self-tests the defibrillator performs, the defibrillator indicates its

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operational status as determined by the self-tests, such as through a visual display. The indication is preferably fail-safe so that a failure of the status indication mechanism itself will result in the indication of an inoperable defibrillator status.

FIG. 1 is a schematic representation of a defibrillator constructed and operated according to this invention. The defibrillator 10 includes a battery 12, a high voltage delivery system 13 (preferably consisting of a capacitor or capacitor bank 14, a capacitor charger 16 and a switching mechanism 18), an electrode connector 20 and a controller 22 that operates the charger and switching mechanism to deliver an electric shock from the capacitor to electrodes connected to the electrode connector or interface 20. The defibrillator has a testing system 24 including a test signal generator 26 and a defibrillator status indicator 28. The purpose of testing system 24 is to test the operational status of the defibrillator's components and to provide an indication of that status automatically in response to predetermined events or conditions and/or periodically on a preset schedule.

While the testing system 24 and controller 22 are shown in FIG. 1 as separate elements, they could be combined into a single element that performs all testing and operational control functions. In addition, the testing system 24 may also include components located within other defibrillator subsystems, such as within the high voltage delivery system. In any event, the testing system communicates with the tested defibrillator components and systems via communication channels to control the tests and to gather information about the status of the tested components. The testing system also communicates indicator control signals to the status indicator via communication channels as well.

FIG. 2 is a schematic drawing showing self-testing subsystems making up testing system 24 in the preferred embodiment. It is not necessary that a given defibrillator include each of the subsystems shown in FIG. 2. According to this invention, the defibrillator must include at least one automatic self-test that is initiated in response to a test signal generated either periodically or as a result of a specified event or condition.

Also, it is not necessary for the apparatus performing each test in each subsystem to be in the same physical location. FIG. 2 is a logical grouping and is not intended to be an actual drawing of a defibrillator or defibrillator subsystem.

Each self-test in each group of FIG. 2 responds to a test initiation signal from signal generator 26, and the result of each self-test in each group affects the status is indicated on status indicator 28. This collection of self-testing subsystems may be added to or subtracted from without departing from the invention. In addition, while there may be other tests performed by the defibrillator that do not meet these criteria, such tests form no part of this invention.

The first testing subsystem is the functionality tester 23. The self-tests performed by this subsystem test the operability and functionality of defibrillator components and/or subsystems. Examples include the testing of switches within the switching mechanism of the high voltage delivery system and the testing of registers within the defibrillator's controller.

The second testing subsystem is the calibration verifier 25. The self-tests performed by this subsystem determine whether certain defibrillator components and/or subsystems meet preset specifications. Examples include determining the capacitance of the defibrillator's capacitor and checking the response of the controller to capacitor voltage values.

The testing system also may include a recalibrator 27 that adjusts a component or subsystem of the defibrillator in

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response to a determination that the component or subsystem is no longer, or no longer operates, at a specified value or within a specified range of values. For example, parameters used by the defibrillator's controller to control operation of the high voltage delivery system may be changed to reflect changes in the values of defibrillator components.

The actual self-tests automatically performed by a defibrillator's testing system depend in part on the defibrillator's structure and in part on reliability goals set by the defibrillator's designer. Trade-offs may be made between the completeness of a given self-test (which adds to the reliability of the defibrillator product) and the cost of implementing a complete and accurate self-test. A particular implementation of a defibrillator and its self-testing system is described below. The discussion merely illustrates a preferred embodiment of the invention. Our invention covers other defibrillator designs and other collections of external defibrillator self-tests as well.

FIG. 3 is a block diagram showing a preferred configuration for the defibrillator of this invention. Some of the elements are described in more detail further below. Defibrillator elements not specifically described in this application may be configured and operated in the manner described in U.S. patent application Ser. No. 08/227,553, "Electrotherapy Method and Apparatus," filed Apr. 14, 1994, the disclosure of which is incorporated herein by reference.

As shown in FIG. 3, defibrillator 30 has a power source such as a removable battery 32, a controller such as CPU 34, and a high voltage delivery system 36 including a capacitor or capacitor bank and appropriate switches (not shown) to deliver a pulse of electrical energy to an electrode connector or interface 38 and then to a patient via electrodes 40. Delivery of the electrical pulse is controlled by CPU 34. A test and isolation relay 76 and a test load 78 are provided for reasons explained below.

An ECG front end system 35 acquires and preprocesses the patient's ECG signals through electrodes 40 and sends the signals to CPU 34 via a system gate array 56. System gate array 56 is a custom application specific integrated circuit (ASIC) that integrates many of the defibrillator's functions, such as display control and many of the instrument control functions, thereby minimizing the number of parts and freeing up main CPU time for use in other tasks. The system gate array could be replaced by discrete logic and/or another CPU, of course, as known in the art.

The external defibrillator shown in FIG. 3 also has a memory device 80 (such as a removable PCMCIA card or a magnetic tape), a microphone 81, a speaker 82, a LCD panel 83 and a set of illuminated push-button controls 84. None of these elements is critical to the present invention.

A system monitor mediates the external defibrillator's self-testing functions by watching for scheduled test times and unscheduled power-on events. The system monitor generates test signals periodically at scheduled times and in response to specified events. The system monitor is also responsible for operating a fail-safe defibrillator status indicator or display. The system monitor communicates test signals to the CPU via a communication channel, and the CPU controls and gathers information from tested defibrillator components via other communication channels, some of which pass through system gate array 56.

In the embodiment shown in FIG. 3, system monitor 42 is separate from CPU 34 so that power can be provided to the system monitor without powering any other part of the defibrillator. Thus, system monitor 42 has its own power

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supply 44 apart from the defibrillator power supply 46, as shown more specifically in FIG. 4. This dedicated power supply 44 draws approximately 30 microamps from battery 32 and is active whenever power is available from the battery. The dedicated system monitor power supply may also have its own battery apart from the main battery.

As shown in more detail in FIG. 4, the other major element of system monitor 42 is a low-power gate array 48. In this preferred implementation, gate array 48 is a 44-pin custom ASIC. Gate array 48 is preprogrammed to perform the functions of the system monitor. As an alternative, the system monitor could be implemented with a low power CPU and/or with discrete logic components.

Gate array 48 operates a 32.768 kHz crystal oscillator to provide the defibrillator testing system's scheduling function. The gate array divides the oscillator's frequency repeatedly to generate periodic (e.g., daily, weekly, monthly) test initiation signals. The system monitor also sends a 32.768 kHz clock signal out on line 52 to be used by the defibrillator system to perform other functions.

In addition to the periodic tests, certain defibrillator self-tests are performed rapidly in response to activation of the defibrillator's ON button (shown schematically as element 54 in FIG. 4) by an operator. Activation of the ON button 54 prompts the system monitor to generate a power-on test initiation signal.

The system monitor indicates the status of the defibrillator as a result of the periodic and power-on self-tests. The status indicator should be fail-safe so that the indicator will indicate an inoperable status if the system monitor should fail. The system monitor communicates control information to the status indicator through communication channels.

In a preferred embodiment, the system monitor 42 powers a status indicator consisting of a visual display 58 and a piezo buzzer 60 to indicate the operational status of the defibrillator to a user. As shown in more detail in FIG. 5, visual display 58 may be a multiple-part LCD 62 powered by the system monitor via AC-coupled drive 72. The top plate 64 of the LCD is a clear window with an "OK" symbol printed on its back. The middle plate 66 is an LCD shutter that is biased so as to be opaque when driven by the system monitor via drive 72. The bottom plate 68 has an international "Not" symbol on its top surface. Middle plate 66 also includes a separately addressable portion 70 driven by the system monitor via AC-coupled drive 74.

In operation, the system monitor 42 drives LCD shutter 66 only when confirmation of successful testing is received within an expected time window. The visual display would then appear as in FIG. 5(d). Failure to receive proper test confirmation within the allotted time window will cause the system monitor to cease issuing drive signals to shutter 66. Shutter 66 will then go transparent to superimpose an international "Not" symbol on the "OK" symbol in the LCD as shown in FIG. 5(c). The system monitor will also then begin powering a piezoelectric failure alert buzzer 60, preferably for 200 msec, every 10 sec, so long as there is power enough to do so.

The primary advantages of the visual display of the preferred embodiment are its low power requirements and the fact that it is powered by an AC signal rather than a DC signal. This latter point ensures the display's fail-safe nature, since the shutter of middle plate 66 cannot be maintained opaque without the active involvement of the system monitor generating the AC signal.

Separately addressable portion 70 serves as a positive indication (in addition to the fail-safe "OK" symbol) that the

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defibrillator has power and is functioning properly. Portion 70 blinks periodically through the alternating driving and releasing of the signal to portion 70 through drive 74.

In an alternative embodiment, an LCD shutter covering an "OK" symbol is driven open to display the "OK" symbol to indicate an operational defibrillator status. The shutter is permitted to close to cover the "OK" symbol to indicate that the defibrillator is not operational. Another alternative category of fail-safe indicators include electromechanical devices, such as those used for aircraft instrumentation.

In response to the generation of a test initiation signal, the system monitor commands the defibrillator's power system to turn on. The CPU then issues an appropriate series of commands to perform the required tests. The tests performed in response to the periodic and power-on test initiation signals are described in more detail further below with reference to the table shown in FIG. 6.

FIG. 6 shows the scheduling of some of the tests that can be performed by the self-test system of this invention. Some of the tests are performed when a battery is inserted, some are performed daily, some are performed weekly, some are performed monthly, some are performed when an operator powers-up the external defibrillator, and some are performed during operation of the defibrillator. FIG. 6 is not an exhaustive list of possible tests, nor is performance of any particular test listed in FIG. 6 essential to the invention. The tests and test groupings shown in FIG. 6 are merely an example illustrating this invention.

The first test grouping is the Battery Insertion Test or BIT. The BIT tests all internal subsystems, allows the user to verify PCMCIA card type, setup parameters, and the proper operation of systems that are only externally observable (e.g., LCD operation and button functionality). The BIT is performed whenever a good battery is inserted into the defibrillator, unless the defibrillator's electrodes are attached to a patient.

The second test grouping shown in FIG. 6 is the Monthly Periodic Self-Test (MPST). The MPST performs the same automated tests as the BIT, but in order to conserve power it does not run the externally observable systems (e.g., LCD, LED's, etc.). The MPST is performed once every 28 days so long as a good battery is maintained in the defibrillator.

The third test grouping shown in FIG. 6 is the Weekly Periodic Self-Test (WPST). The WPST performs essentially the same automated tests as the MPST, except the test shock is not performed in order to conserve power. The WPST is performed once every 7 days so long as a good battery is maintained in the defibrillator.

The fourth test grouping shown in FIG. 6 is the Daily Periodic Self-Test (DPST). The DPST performs fewer tests than the WPST in order to conserve power.

The fifth test grouping shown in FIG. 6 is the Power-On Self-Test (POST). The POST is performed whenever an operator turns the defibrillator from OFF to ON in preparation for use of the defibrillator on a patient. The tests performed in the POST are selected to provide the highest confidence of instrument functionality in the shortest possible time.

The final grouping of tests in FIG. 6 is the Runtime Tests. These tests are performed continually during runtime to assess the safety and effectiveness of portions of the defibrillator. The tests are explained in more detail below.

The self-tests listed in FIG. 6 are not necessarily listed in the order performed. The performance order depends in part on the interrelationship of the components and functions

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tested. To the extent there is no such relationship, then the self-test order is arbitrary.

In general, failure of a self-test results in an indication of an inoperable status or error status by the defibrillator's status indicator. For example, in the defibrillator described above, failure of a self-test would result in the display of the "Not OK" symbol by the system monitor and activation of the audible failure signal. The system monitor takes this action if it receives a signal from the CPU or from the system gate array that a test has failed (i.e., that a tested component is not functional or that the component's calibration could not be verified) or if the system monitor does not receive information showing that the currently-scheduled self-test has passed before the expiration of the watchdog's time-out period (e.g., 200 msec).

In a preferred embodiment of this invention, self-test scheduling and result information may be stored in system memory for later diagnosis of the defibrillator by a technician or operator. For example, in the defibrillator described above, date and time information regarding the self-tests performed are stored in internal memory and/or in the removable memory 80 (e.g., PCMCIA card) so that a history of performed tests can be obtained by a technician or operator. In addition, if a self-test indicates that a component or subsystem is not functional or is out of calibration, or if any recalibration has been performed, detailed information about that test is stored in internal memory and/or in removable memory. Information regarding environmental conditions (temperature, humidity, moisture, impacts) may also be stored for use in later diagnosis.

The CPU self-test is a functional test. During the CPU self-test the CPU tests its internal register integrity and verifies its access to local and external memory locations. If the CPU does not pass these initial tests, it attempts to notify the user of a system failure by writing to a system failure register in the system monitor, resulting in a status display showing "Not OK". If the CPU does not respond to the system monitor within 200 msec of power on, the system monitor assumes the CPU is dead, and the "Not OK" symbol is displayed.

The System Gate Array self-test is also a functional test. In the System Gate Array self-test, the CPU verifies that it can write to and read from the system gate array register set. This test also tests other components of the system gate array, such as whether defibrillator waveform control state machines are functioning correctly. Test failures are handled as for the CPU self-test above.

The System Monitor Gate Array self-test is a functional test as well. The System Monitor Gate Array self-test verifies that the CPU can write to and read from the system monitor.

At the beginning of the Program ROM CRC (Cyclic Redundancy Check) self-test, the CPU resets the system monitor watchdog and executes a CRC on program ROM. This test is a functional test.

In the System RAM Checksum self-test (a functional test), RAM used for data memory is verified using a test pattern that has a high probability of identifying both address and data faults within RAM. Once the pattern has been written to system RAM, the test calculates a checksum based on the system RAM contents.

In the Video RAM Checksum self-test, RAM used for video memory is verified in the same-manner as for the system RAM. This self-test is a functional test.

In the Device Flash ROM Checksum self-test, a checksum of the voice data pointer and voice data record is

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calculated and compared with the checksum value stored in the internal flash ROM. This self-test is a functional test as well.

In the System Watchdog Verify self-test, the CPU verifies the watchdog by writing a known watchdog time-out into the watchdog register and looping until the watchdog time-out register in the system monitor indicates that the watchdog timer has expired. During this test, the watchdog outputs, NMI, and RESET are disabled. The CPU signals a failure if the watchdog timer does not expire within the expected time frame.

The PCMCIA Card Verify self-test is a functional test that checks for the presence and type of the removable memory.

The next four self-tests listed in FIG. 6—Front End Gain, Artifact System, CMR Channel, and Defibrillator Connector/Relay—are all part of the ECG front end tests. These tests verify the functionality and verify the calibration of the ECG input circuitry and the patient/electrode connection circuitry. These tests are not performed during the POST since the tests assume that there is no load attached to the defibrillator output connector.

An explanation of some special features of the external defibrillator of this invention is required as background for the ECG front end tests. FIG. 7 shows the ECG front end 35 in relationship to the system gate array 56, the high voltage delivery system 36, a test and isolation relay 76 and the patient connector 38, as well as communication channels among some of these elements. The test and isolation relay 76 is normally in the state shown in FIG. 7 so that no shock can be delivered from the high voltage delivery system 36 to the patient connector 38 and to the electrodes 40 attached to a patient.

In this state, any signals from electrodes 40 will pass through a pair of protective resistors 86 and 88 to an ECG amplifier 90. A high resolution A/D converter 92 digitizes the ECG data and sends it to the system gate array 56 for processing by the CPU to determine whether a shock is required. The system gate array 56 also sends control signals to the A/D converter 92.

The ECG front end 35 also has a patient/electrode connection tester consisting of a signal generator 94 connected to the ECG signal input lines through a pair of protection resistors. The signal generator 94 receives input from the ECG analog output and carrier frequency commands from the gate array. The patient/electrode connection tester also produces an artifact test signal which is sent through ECG amplifier 90 to the CPU via line 98. ECG signal collection and analysis and artifact detection are not part of the present invention.

During automated testing, the system gate array 56 uses the signal generator 94 as a test signal injector to verify the function of the various ECG front end elements, wiring to the patient connector 38, and the normally-open contacts of the test and isolation relay 76. To test the ECG processing elements, the system gate array 56 causes the signal generator 94 to inject a small, low-frequency signal mimicking the amplitude and frequency characteristics of an ECG signal, thereby simulating a patient being monitored by the defibrillator. As the frequency of this test signal is varied, the digital data stream from the system gate array is checked by the CPU for values indicative of proper gain and filtering characteristics of the ECG front end, thus verifying the functionality and calibration of the analog and A/D conversion pathways.

In the Defibrillator Connector/Relay self-test, the function of the test and isolation relay contacts 100 and 102 and

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patient connector wiring are tested. The system gate array 56 causes the signal generator 94 to emit a 100 microamp, 600 Hz test signal and concurrently switches the test and isolation relay 76 to the normally-open position (shown in phantom in FIG. 7). The test current signal is carried to a 4-wire connection 104 and 106 directly on the patient connector contacts, through the relay common connection, and into the high voltage delivery subsystem 36, where both signal lines are held at ground potential. The relay 76 is then switched to its normally closed position. Carrier voltage is measured in both positions is indicative of the resistance of the circuit tested. When the relay is in normally open position, the carrier voltage should be approximately equal to the full scale voltage of signal generator 94. When the relay is in the normally closed position, carrier voltage should be approximately zero.

Finally, in the Artifact System self-test, the system gate array causes the signal generator 94 to emit signals indicative of artifact generation at the electrodes. Proper receipt of artifact signals of the expected amplitude at the CPU verifies the function and calibration of this channel.

There are three battery-related self-tests that are members of each of the test groupings in the preferred embodiment. The battery tests described below are based on a defibrillator design using the battery capacity indicator described in U.S. patent application Ser. No. 08/182,605, filed Jan. 14, 1994, now U.S. Pat. No. 5,483,165. (specifically, the embodiment of FIG. 2) the disclosure of which application is incorporated herein by reference. Other battery charge sensor arrangements and other battery charge subsystem self-tests may be used, of course, without departing from the scope of the invention.

The Battery Sense Cell Measurement self-test listed in FIG. 6 refers to a battery capacity test described in Ser. No. 08/182,605 in which a parameter of a single battery cell is monitored to determine the remaining capacity of the entire battery. In the preferred defibrillator configuration, this functional self-test determines whether the remaining battery capacity is sufficient for performing one more use of the defibrillator by determining whether the voltage of the sense battery cell is above a threshold value of approximately 2 volts. If not, then a Low Battery Warning State is entered. If this state is entered during a BIT, DPST, WPST or MPST, the unit returns to Stand-by mode displaying the "Not OK" symbol. If this state is entered during a POST or during runtime, the user is alerted by a symbol appearing on the LCD display 83 and with an audible prompt.

The second listed battery self-test is the Battery Sense Cell Load Check. This calibration verification self-test verifies the sense cell additional load circuitry described in Ser. No. 08/182,605 by turning the additional load circuitry on and off and measuring the voltage load across the load resistor. This test can actually be performed while performing the first battery self-test.

The third listed battery self-test is the Battery Stack Check. This functional test measures the voltage of the entire battery cell stack as a cross-check against the Battery Sense Cell Measurement test. If a portion of the battery stack other than the sense cell has been damaged, the voltage of the entire stack could be different than that which would have been expected based on the sense cell test.

In the Power Supplies Check calibration verification self-test, the system monitor activates the defibrillator's power supply system to supply power to all of the instrument's elements. Scaled representations of the voltages from the supplies are input for verification to the main CPU A/D

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converter. For example, the major power supplies are: +18 volt switched battery; +5 volt for system monitor; +5 volts for main logic and analog; -5 volt for analog only; -14 to -22 volt CPU adjustable for LCD bias; +20 volts for IGBT switch drives; +2.5 volt reference for ECG front end; +5 volt reference for main CPU A/D converter; and 50 ma current source supply for LCD backlight (tested by voltage developed). In addition, the high voltage supply is tested by its ability to charge the capacitor.

The HV Isolation Relay self-test determines the functionality of the test and isolation relay 76. In the first part of the test, the system gate array 56 moves the test and isolation relay to its normally open position, i.e., with the switches against contacts 106 and 102. The ECG front end measures the impedance across conductors 96 and 97. If the measured impedance corresponds to a predetermined impedance value, then the relay passes this part of the test.

The ECG front end then measures the impedance across conductors 96 and 97 with the test and isolation relay 76 in the normally closed position shown in FIG. 7. The measured impedance should be high (>14k Ohms). If not, either a load is present at electrodes 40 or the relay failed to move completely to the normally closed position. In either case, the test fails, and the system monitor displays the "Not OK" symbol on the status indicator. In addition, failure to meet both parts of the Isolation Relay test prevents the defibrillator from performing the High Voltage Discharge Test described below.

Under normal conditions, the defibrillator used to implement and practice the preferred embodiment of this invention delivers a biphasic waveform to the patient, as described in more detail in U.S. patent application Ser. No. 08/227,553 now U.S. Pat. No. 5,607,454. FIG. 8 provides further information regarding the preferred defibrillator's high voltage delivery system and how its operation is verified and calibrated during self-test.

High voltage delivery system 36 has a capacitor or capacitor bank 112 which can be charged to a preset voltage through a high voltage charger 114 connected to the power supply system 46 and battery 32. Operation of the high voltage charger is controlled by system gate array 56. A high voltage switch 110 consisting of five switches A-E and a shunt resistor R_{BITE} controls delivery of the biphasic waveform from capacitor 112 to the patient connector 38 through test and isolation relay 76 under the control of system gate array 56.

Information regarding charge, current and voltage parameters at the capacitor is provided to system gate array 56 by a current and charge measurement device 116, an overvoltage detector 118 and a voltage divider 120. As described in more detail in Ser. No. 08/227,553, current and charge measurement device 116 is preferably a comparator that trips when a preset charge amount has been transferred from capacitor 112. The time required for this charge transfer is determined by system gate array 56 and is used to determine first and second phase durations via a look-up table in system gate array 56. All information and control signals pass among the elements via communication channels, some of which are shown schematically in FIG. 8.

As explained in Ser. No. 08/227,553, resistor R_{BITE} is part of an overcurrent protection mechanism to protect circuit components from the effects of high current in the event that the impedance load between electrodes 40 is too low. Unless the initial current as measured by current and charge measurement device 116 is below a preset threshold, R_{BITE} is kept in the waveform delivery circuit to limit the current flowing from capacitor 112 through the switching mechanism 110.

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The high voltage delivery system has an overvoltage protector that protects switching circuit components from the effects of excessive voltage in the event of a higher than expected patient load resistance by preventing any transition from a first biphasic waveform phase to a second biphasic waveform phase. Analog voltage information from the capacitor is fed from a voltage divider 122 to an overvoltage detector 118. Overvoltage detector 118 is preferably a comparator that trips at a preset voltage. The status of the comparator is communicated to system gate array 56, which controls operation of the switching mechanism 110.

Finally, analog information regarding the charge state of capacitor 112 is sent to CPU 34 via voltage divider 120, where it is converted to digital form. This capacitor voltage information is used by the CPU to control capacitor charging.

The High Voltage Delivery Subsystem self-test actually includes a number of individual self-tests. Capacitor 112 is charged to full voltage (e.g., approx. 1710 volts). As the capacitor voltage rises, the calibration of the overvoltage detector 118 is checked to see that it trips at the proper threshold voltage. If it fails to trip, the system gate array returns a signal to the system monitor to show "Not OK" on the status indicator.

After the capacitor has been fully charged, the system gate array 56 sets the high voltage switch 110 to its normal initial discharge position (switches A and E closed, all other switches open) and commences discharge of the capacitor through the test and isolation relay 76 to the test load resistance R_L . R_L simulates the load of a patient to whom the defibrillators electrodes may be attached. R_L is preferably approximately 10 ohms, however, which is smaller than the minimum allowable patient resistance for the defibrillator. This low resistance assures that the test stresses all of the elements tested in the high current pathways for worst-case patient conditions.

During this part of the High Voltage Delivery self-test, the system gate array verifies overcurrent detection calibration by determining whether the CPU correctly identifies the overcurrent condition detected by current and charge measurement device 116. The system gate array also checks for proper operation of the charge threshold detector and that the overvoltage detector 118 trips properly when the capacitor voltage drops below the safe voltage threshold, in both cases by determining whether these events occur at their expected times. If either of these parameters is not its expected value, the system monitor displays "Not OK" on the status indicator.

As the capacitor voltage drops during discharge through the test load, the current measured by the current and charge measurement device 116 drops as well. The CPU marks the time the current drops below the overcurrent threshold (t_0). As the current continues to fall, the CPU marks the time (t_1) that the current reaches a value that is 37% of the overcurrent threshold. The difference of these two times is the time constant given by the product of the capacitor value C and the series resistance:

$$t_1 - t_0 = (R_L + R_{BATT}) * C.$$

Switch D is then closed to short out R_{BATT} . This results in another overcurrent situation, and the CPU once again marks the time (t_2) of capacitor decay to the overcurrent threshold and the time (t_3) to 37% of the threshold. Since R_{BATT} has been removed,

$$t_3 - t_2 = R_L * C.$$

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Since the time measurements can be made very accurately, the relationships between the resistive and capacitive components (and therefore their calibration) can be verified very accurately as well:

$$\frac{t_1 - t_0}{t_3 - t_2} = \frac{R_L + R_{BATT}}{R_L}$$

$$C = \frac{t_3 - t_2}{R_L}$$

If the calculated resistance value differs from the expected value by more than a predetermined amount (e.g., 1%), or if the calculated capacitance value differs from the expected value by more than a predetermined amount (e.g., 5%), the system monitor displays the "Not OK" symbol.

In the preferred embodiment, the gain of the comparators of the current and charge measurement subsystems are determined by the particular values of the components used during assembly of the device. Due to allowable tolerance variation of the components, the times that the currents pass associated threshold values (t_0 and t_2) may vary from ideal values ($t_0(\text{ideal})$ and $t_2(\text{ideal})$). Actual values of t_0 and t_2 are measured during self-test of the instrument and compared to stored $t_0(\text{ideal})$ and $t_2(\text{ideal})$. If the actual values of t_0 and t_2 measured during the High Voltage Discharge Test differ from the ideal values by less than a preset amount, then the gain on the comparator of the current and charge measurement device 116 is automatically recalibrated by the CPU to a range closer to the ideal value. If the actual values differ from the ideal by the preset amount or more, the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

In a similar manner, the expected time for times for the measured charge delivery to cross the charge threshold used to determine first and second phase durations in normal operation is compared to the actual time. If the difference is less than a preset value, the CPU recalibrates the phase durations by recalculating the phase duration values according to a predetermined equation and storing the new values in the look-up table. Alternatively, the CPU could simply replace the original look-up table with another that is correlated with a particular time difference. If the time difference is equal to or greater than the preset value, then the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

Another feature of the external defibrillator of preferred embodiment is an undercurrent detector. If the patient to whom the electrodes are attached has an impedance greater than a specified value, or if one of the electrodes has become dislodged or unattached, in normal operation the defibrillator's discharge will abort. This condition is detected by the current and charge measurement device 116 in conjunction with the CPU.

The High Voltage Delivery self-test verifies calibration of the undercurrent detector by determining whether the low current condition is detected as the capacitor continues its discharge and the discharge current falls. If the CPU fails to detect the undercurrent condition, the test fails and the system monitor displays the "Not OK" symbol on the status indicator.

After the capacitor has completely discharged, it is recharged and discharged through the second current path by opening all switches in high voltage switch 110, then closing switches B and C. Many of the same parameters described above can be measured to verify the functionality of switches B and C.

The Waveform Delivery self-test is performed only while the defibrillator is operating in normal mode (e.g., connected

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to a patient). The defibrillator evaluates the measured and calculated waveform parameters after each delivered shock to determine if the waveform was delivered as expected. For example, if the defibrillator is constructed and operated according to U.S. patent application Ser. No. 08/227,553, the defibrillator will analyze waveform parameters such as start voltage, phase 2 end voltage, phase 1 duration and phase 2 duration. If the delivered waveform parameters cannot be reconciled with other information available to the defibrillator, the defibrillator warns the operator of a potential fault condition by, e.g., displaying a warning on the defibrillator's LCD.

The three Calibration Standard self-tests are an automatic way of verifying that defibrillator system standards have not drifted out of calibration. The standards are the values of R_L , R_{BIT} , the system monitor clock, the CPU clock, the CPU A/D convertor reference voltage and the ECG front end A/D convertor reference voltage. For all test groupings except the run time test, the voltage references are checked against each other to determine if either has drifted far enough from its expected value to affect the accuracy of the defibrillator. Specifically, the analog reference voltage for the ECG front end A/D convertor (which has an expected value of 2.5 volts in the preferred embodiment) is measured by the CPU A/D convertor. If the measured digital value differs from 2.5 volts by more than a predetermined tolerance, then at least one of the two reference voltages (i.e., either the ECG front end A/D convertor reference voltage or the CPU A/D convertor reference voltage) has drifted so far so as to affect the reliability of the device.

The time references are cross-checked in a similar way. The CPU counts the clock pulses from the system monitor clock for a predetermined amount of time (as measured by the CPU clock). If the number of counted system monitor clock pulses differs from its expected value by more than a predetermined amount, then at least one of the two clocks has drifted out of the tolerance range.

In addition, as discussed above, the High Voltage Delivery self-test cross-checks the values of R_L and R_{BIT} . Verification of the calibration of all three sets of reference variables is a prerequisite to the overcurrent detection calibration and charge threshold detection calibration described above.

In normal stand-by mode, the contacts beneath all buttons should be open. The Stuck Button self-test determines whether any of the contacts are closed. If so, the test returns a "Not OK" signal.

The remaining tests require user intervention and/or observation and are therefore part of only the BIT or POST test groupings. In the Button test, the user is prompted to

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depress identified buttons on the instrument to determine whether the buttons are functioning properly. All of the other tests run without user intervention. They each require the user to observe that the defibrillator elements tested are functioning correctly.

In addition to performing the self-tests according to the periodic schedule and in response to the battery insertion and operation of the defibrillator (as shown in FIG. 6), a group of self-tests can be performed automatically in response to environmental events, such as mechanical shock, e.g. as in a fall (as measured by an accelerometer); vibration (also as measured by an accelerometer); the invasion of moisture into the defibrillator housing (as measured by a humidity sensor); or exposure of the defibrillator to temperature extremes (as measured by a thermocouple, thermistor or other temperature sensor).

Variations of the structure and methods described above are within the scope of this invention. Tests and test structures may be tailored to meet the needs of a particular defibrillator design and its intended use environment.

What is claimed is:

1. A method of performing a self-test in an external defibrillator, the method comprising the following steps:

generating a test signal automatically;

turning on a power system within the external defibrillator in response to the test signal; and

performing a plurality of automatic self-tests within the external defibrillator for determining the status of the defibrillator.

2. The method of claim 1 wherein the turning on step comprises providing power to a central processing unit to perform the self-tests.

3. The method of claim 1 wherein the generating step comprises generating a test signal automatically upon a predetermined event or condition.

4. The method of claim 1 wherein the generating step comprises generating a test signal periodically.

5. The method of claim 1 wherein the performing step comprises performing said plurality of automatic self-tests within the external defibrillator on a schedule.

6. The method of claim 5 wherein the performing step comprises performing a first automatic self-test on a first periodic schedule.

7. The method of claim 6 wherein the performing step comprises performing a second automatic self-test on a second periodic schedule.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,800,460
DATED : September 1, 1998
INVENTOR(S) : Powers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

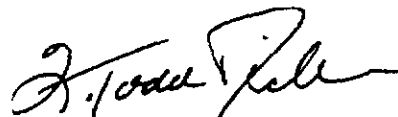
Column 6, (line 25), after "operation of the" insert --external--.

Column 7, (line 64), delete "same-manner" and insert therefor --same manner--.

Column 10, (line 33), after "preferred" insert --external--.

Signed and Sealed this
Twenty-eighth Day of September, 1999

Attest:



Q. TODD DICKINSON

Attesting Officer

Acting Commissioner of Patents and Trademarks

Exhibit D



US006047212A

United States Patent [19][11] Patent Number: **6,047,212**

Gliner et al.

[45] Date of Patent: ***Apr. 4, 2000**[54] **EXTERNAL DEFIBRILLATOR CAPABLE OF DELIVERING PATIENT IMPEDANCE COMPENSATED BIPHASIC WAVEFORMS**[75] Inventors: **Bradford E. Gliner, Bellevue; Thomas D. Lyster, Bothwell; Clinton S. Cole, Kirkland; Daniel J. Powers; Carlton B. Morgan, both of Bainbridge Island, all of Wash.**[73] Assignee: **Heartstream, Inc., Seattle, Wash.**

[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

[21] Appl. No.: **08/946,843**[22] Filed: **Oct. 8, 1997****Related U.S. Application Data**

[63] Continuation of application No. 08/803,094, Feb. 20, 1997, Pat. No. 5,735,879, which is a continuation of application No. 08/103,837, Aug. 6, 1993, abandoned.

[51] Int. Cl.⁷ **A61N 1/39**[52] U.S. Cl. **607/7; 607/5; 607/74; 607/8**[58] Field of Search **607/4-8, 74**[56] **References Cited****U.S. PATENT DOCUMENTS**

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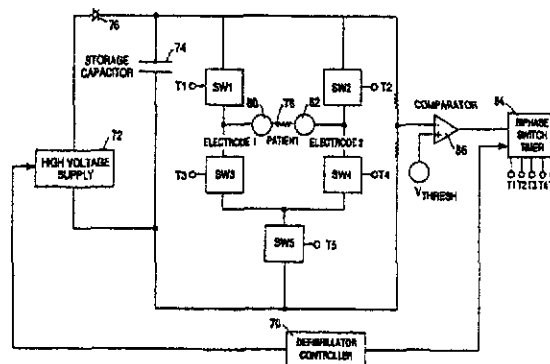
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Primary Examiner—Kennedy J. Schaezle[57] **ABSTRACT**

1c;.5q This invention provides an external defibrillator and defibrillation method that automatically compensates for patient-to-patient impedance differences in the delivery of electrotherapeutic pulses for defibrillation and cardioversion. In a preferred embodiment, the defibrillator has an energy source that may be discharged through electrodes on the patient to provide a biphasic voltage or current pulse. In one aspect of the invention, the first and second phase duration and initial first phase amplitude are predetermined values. In a second aspect of the invention, the duration of the first phase of the pulse may be extended if the amplitude of the first phase of the pulse fails to fall to a threshold value by the end of the predetermined first phase duration, as might occur with a high impedance patient. In a third aspect of the invention, the first phase ends when the first phase amplitude drops below a threshold value or when the first phase duration reaches a threshold time value, whichever comes first, as might occur with a low to average impedance patient. This method and apparatus of altering the delivered biphasic pulse thereby compensates for patient impedance differences by changing the nature of the delivered electrotherapeutic pulse, resulting in a smaller, more efficient and less expensive defibrillator.

12 Claims, 7 Drawing Sheets

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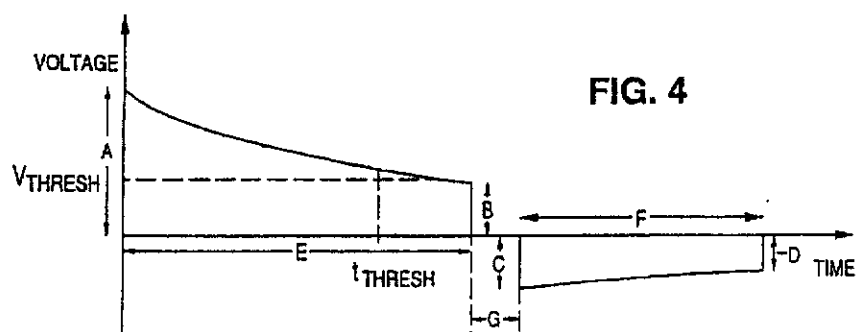
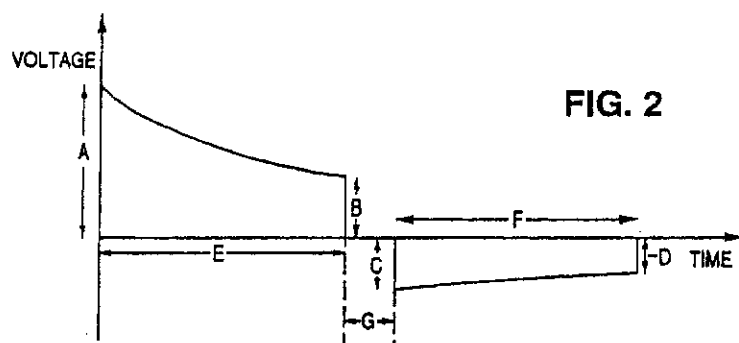
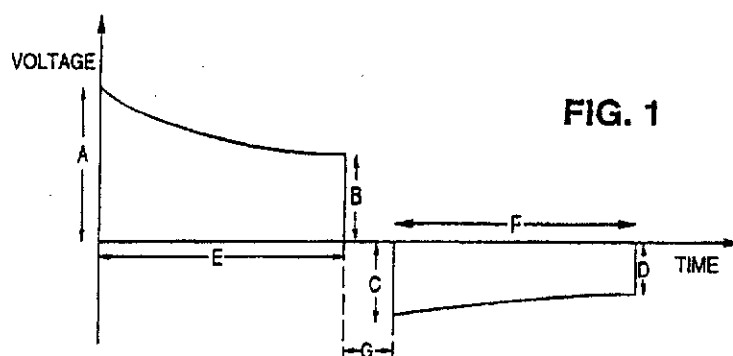
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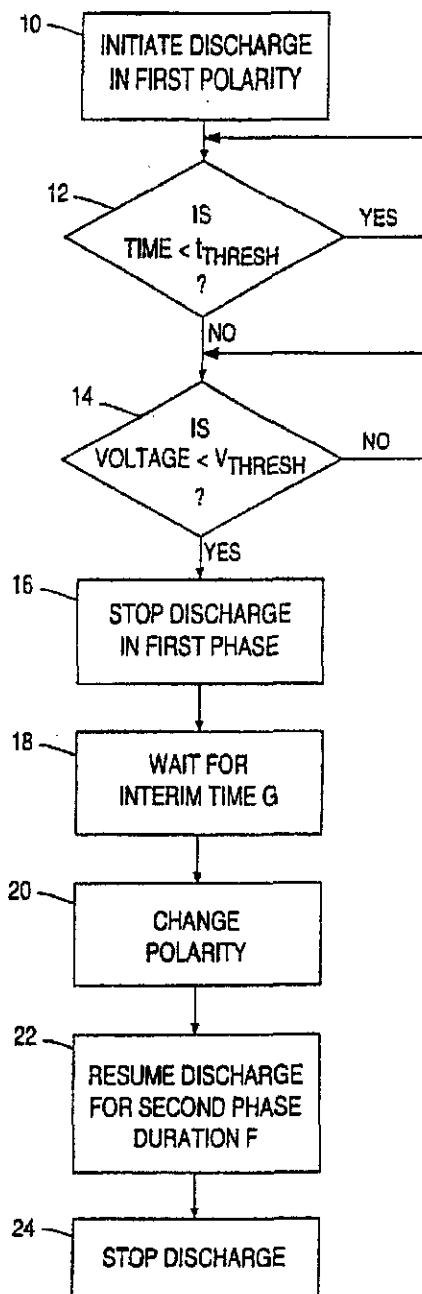


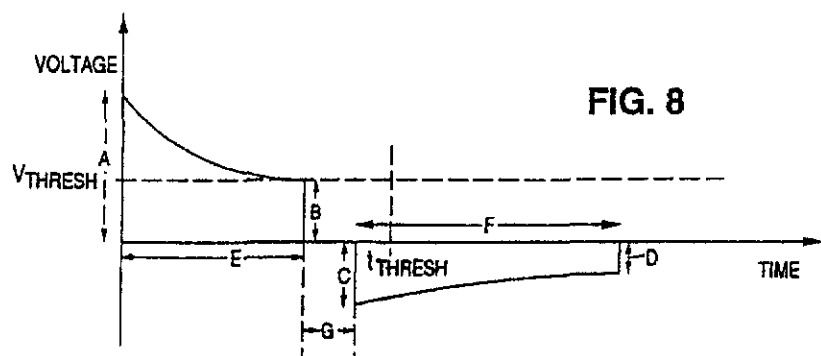
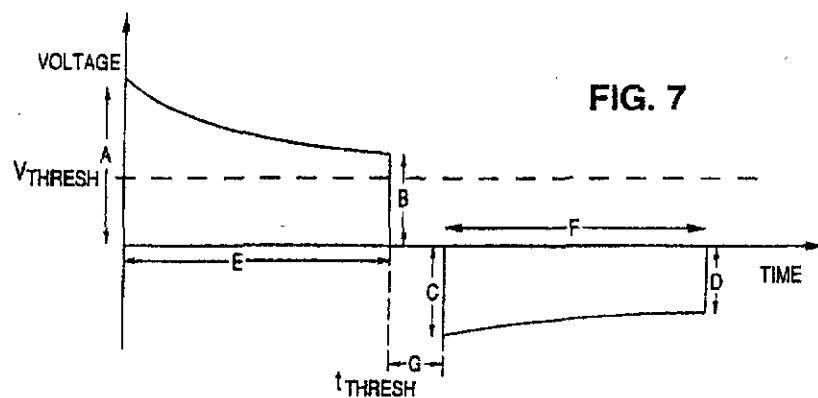
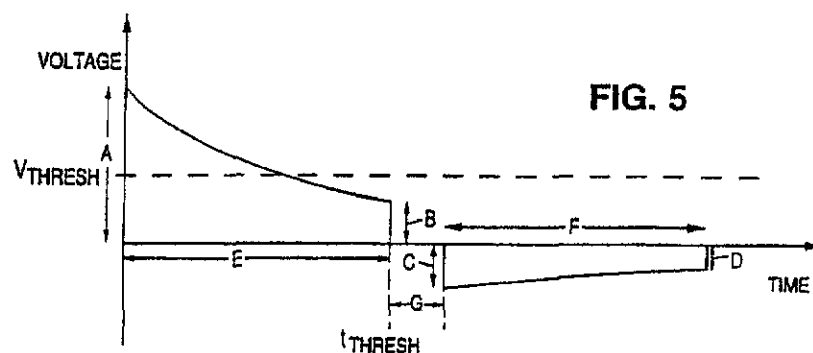
FIG. 3

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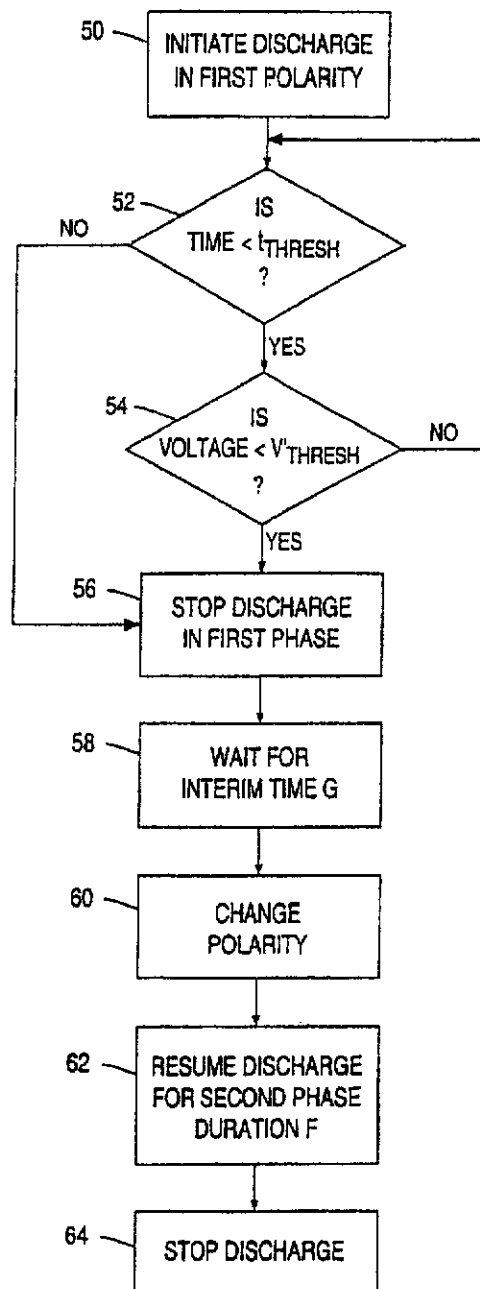


FIG. 6

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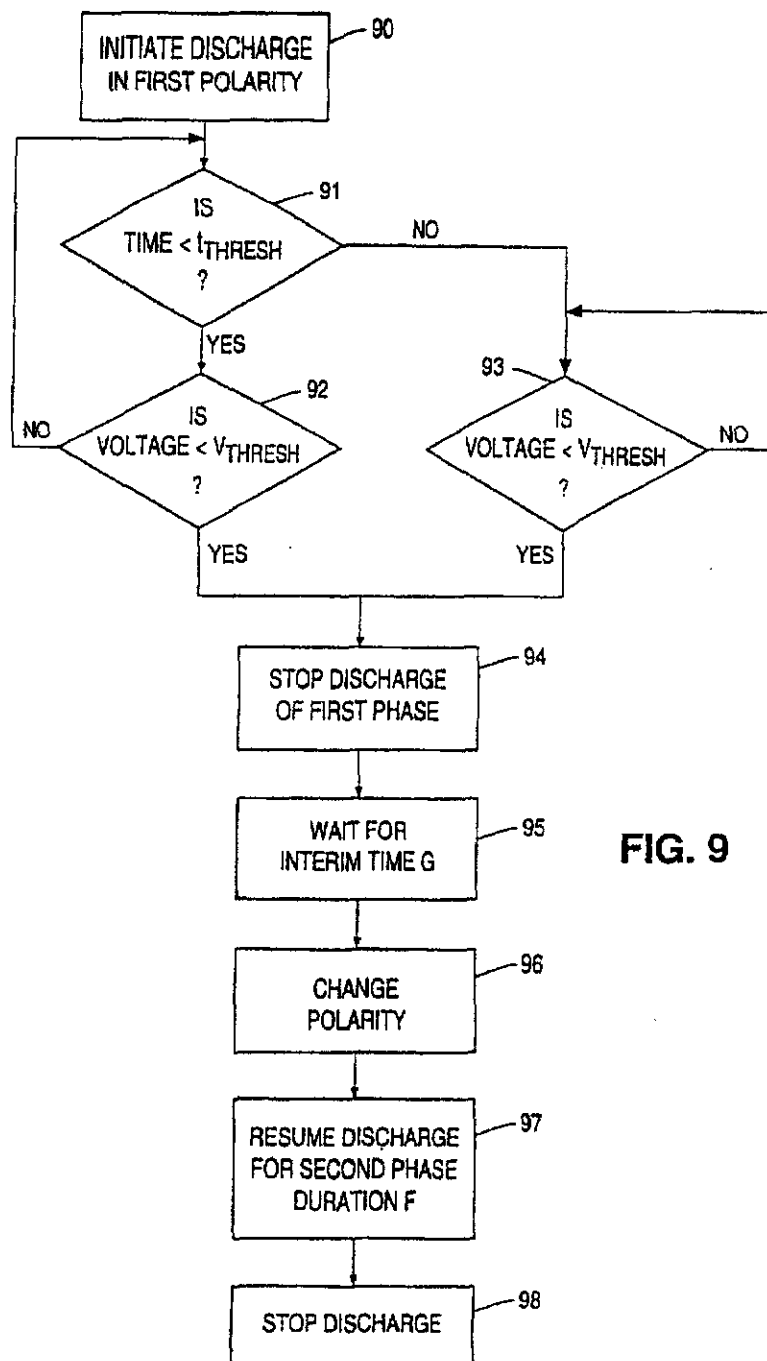


FIG. 9

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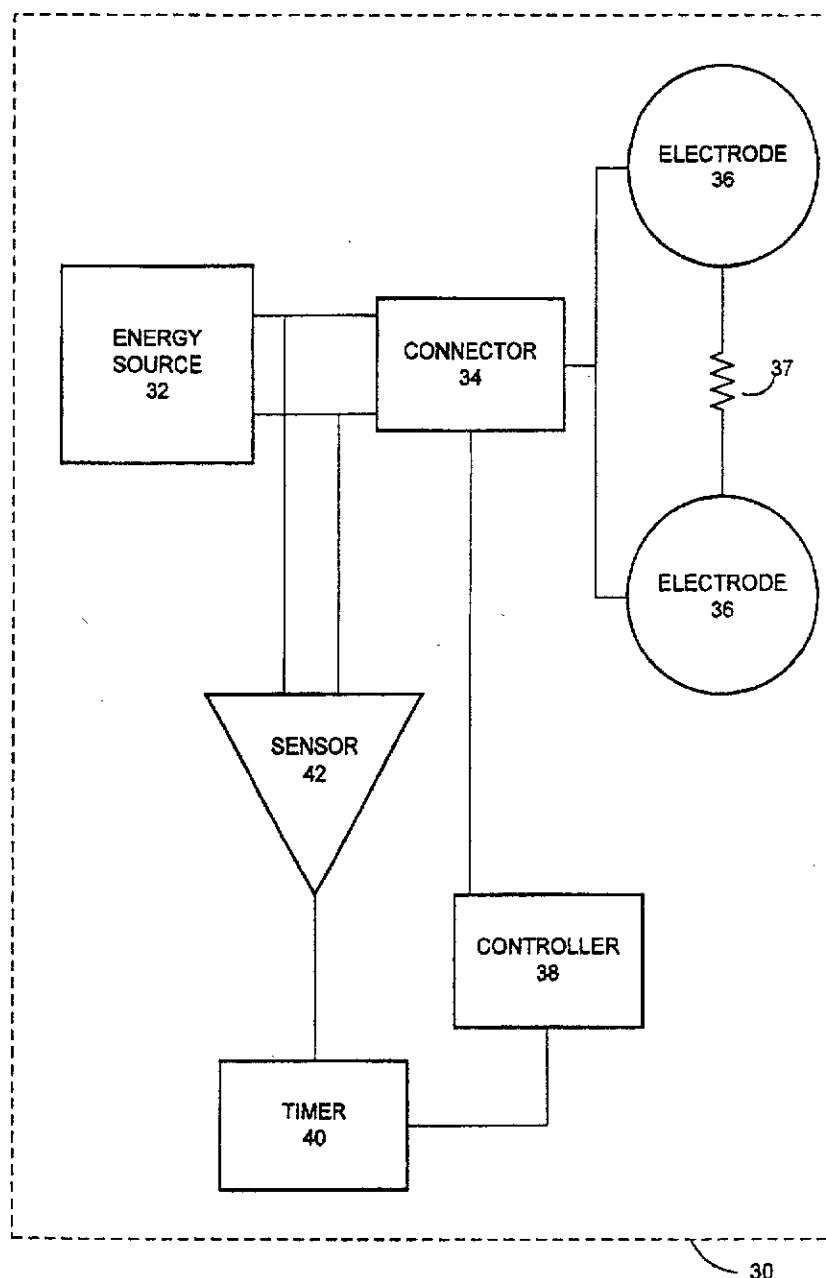


FIG. 10

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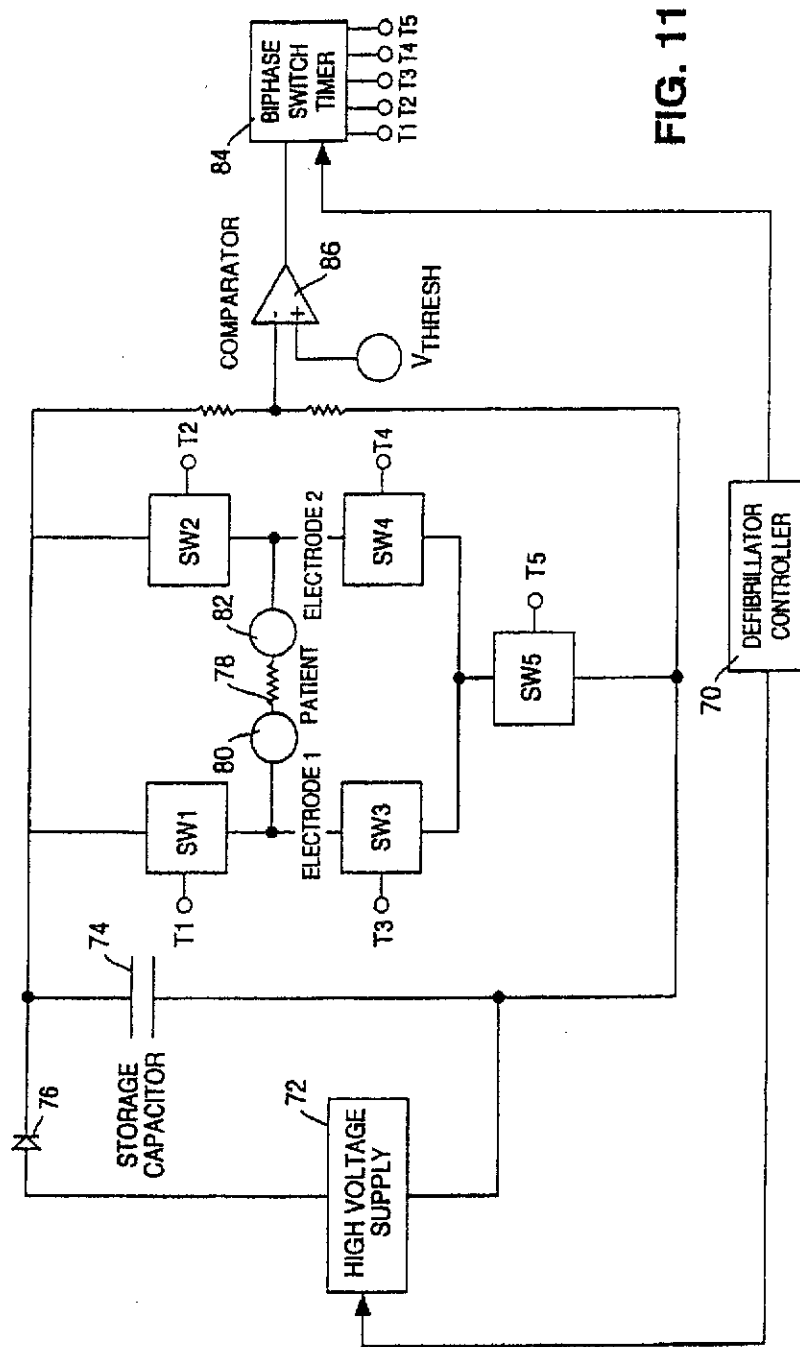


FIG. 11

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EXTERNAL DEFIBRILLATOR CAPABLE OF DELIVERING PATIENT IMPEDANCE COMPENSATED BIPHASIC WAVEFORMS

This application is a continuation of application Ser. No. 08/803,094 filed Feb. 20, 1997, now U.S. Pat. No. 5,735,879, which is a continuation of application Ser. No. 08/103,837 filed Aug. 6, 1993, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates generally to an electrotherapy method and apparatus for delivering a shock to a patient's heart. In particular, this invention relates to a method and apparatus for using an external defibrillator to deliver a biphasic defibrillation shock to a patient's heart through electrodes attached to the patient.

Defibrillators apply pulses of electricity to a patient's heart to convert ventricular arrhythmias, such as ventricular fibrillation and ventricular tachycardia, to normal heart rhythms through the processes of defibrillation and cardioversion, respectively. There are two main classifications of defibrillators: external and implanted. Implantable defibrillators are surgically implanted in patients who have a high likelihood of needing electrotherapy in the future. Implanted defibrillators typically monitor the patient's heart activity and automatically supply electrotherapeutic pulses directly to the patient's heart when indicated. Thus, implanted defibrillators permit the patient to function in a somewhat normal fashion away from the watchful eye of medical personnel.

External defibrillators send electrical pulses to the patient's heart through electrodes applied to the patient's torso. External defibrillators are useful in the emergency room, the operating room, emergency medical vehicles or other situations where there may be an unanticipated need to provide electrotherapy to a patient on short notice. The advantage of external defibrillators is that they may be used on a patient as needed, then subsequently moved to be used with another patient. However, because external defibrillators deliver their electrotherapeutic pulses to the patient's heart indirectly (i.e., from the surface of the patient's skin rather than directly to the heart), they must operate at higher energies, voltages and/or currents than implanted defibrillators. The high energy, voltage and current requirements have made current external defibrillators large, heavy and expensive, particularly due to the large size of the capacitors or other energy storage media required by these prior art devices.

The time plot of the current or voltage pulse delivered by a defibrillator shows the defibrillator's characteristic waveform. Waveforms are characterized according to the shape, polarity, duration and number of pulse phases. Most current external defibrillators deliver monophasic current or voltage electrotherapeutic pulses, although some deliver biphasic sinusoidal pulses. Some prior art implantable defibrillators, on the other hand, use truncated exponential, biphasic waveforms. Examples of biphasic implantable defibrillators may be found in U.S. Pat. No. 4,821,723 to Baker, Jr., et al.; U.S. Pat. No. 5,083,562 to de Coriolis et al.; U.S. Pat. No. 4,800,883 to Winstrom; U.S. Pat. No. 4,850,357 to Bach, Jr.; and U.S. Pat. No. 4,953,551 to Mehra et al.

Because each implanted defibrillator is dedicated to a single patient, its operating parameters, such as electrical pulse amplitudes and total energy delivered, may be effectively titrated to the physiology of the patient to optimize the defibrillator's effectiveness. Thus, for example, the initial

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voltage, first phase duration and total pulse duration may be set when the device is implanted to deliver the desired amount of energy or to achieve that desired start and end voltage differential (i.e., a constant tilt).

In contrast, because external defibrillator electrodes are not in direct contact with the patient's heart, and because external defibrillators must be able to be used on a variety of patients having a variety of physiological differences, external defibrillators must operate according to pulse amplitude and duration parameters that will be effective in most patients, no matter what the patient's physiology. For example, the impedance presented by the tissue between external defibrillator electrodes and the patient's heart varies from patient to patient, thereby varying the intensity and waveform shape of the shock actually delivered to the patient's heart for a given initial pulse amplitude and duration. Pulse amplitudes and durations effective to treat low impedance patients do not necessarily deliver effective and energy efficient treatments to high impedance patients.

Prior art external defibrillators have not fully addressed the patient variability problem. One prior art approach to this problem was to provide the external defibrillator with multiple energy settings that could be selected by the user. A common protocol for using such a defibrillator was to attempt defibrillation at an initial energy setting suitable for defibrillating a patient of average impedance, then raise the energy setting for subsequent defibrillation attempts in the event that the initial setting failed. The repeated defibrillation attempts require additional energy and add to patient risk. What is needed, therefore, is an external defibrillation method and apparatus that maximizes energy efficiency (to minimize the size of the required energy storage medium) and maximizes therapeutic efficacy across an entire population of patients.

SUMMARY OF THE INVENTION

This invention provides an external defibrillator and defibrillation method that automatically compensates for patient-to-patient impedance differences in the delivery of electrotherapeutic pulses for defibrillation and cardioversion. In a preferred embodiment, the defibrillator has an energy source that may be discharged through electrodes on the patient to provide a biphasic voltage or current pulse. In one aspect of the invention, the first and second phase duration and initial first phase amplitude are predetermined values. In a second aspect of the invention, the duration of the first phase of the pulse may be extended if the amplitude of the first phase of the pulse fails to fall to a threshold value by the end of the predetermined first phase duration, as might occur with a high impedance patient. In a third aspect of the invention, the first phase ends when the first phase amplitude drops below a threshold value or when the first phase duration reaches a threshold time value, whichever comes first, as might occur with a low to average impedance patient. This method and apparatus of altering the delivered biphasic pulse thereby compensates for patient impedance differences by changing the nature of the delivered electrotherapeutic pulse, resulting in a smaller, more efficient and less expensive defibrillator.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic representation of a low-tilt biphasic electrotherapeutic waveform according to a first aspect of this invention.

FIG. 2 is a schematic representation of a high-tilt biphasic electrotherapeutic waveform according to the first aspect of this invention.

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FIG. 3 is a flow chart demonstrating part of an electrotherapy method according to a second aspect of this invention.

FIG. 4 is a schematic representation of a biphasic waveform delivered according to the second aspect of this invention.

FIG. 5 is a schematic representation of a biphasic waveform delivered according to the second aspect of this invention.

FIG. 6 is a flow chart demonstrating part of an electrotherapy method according to a third aspect of this invention.

FIG. 7 is a schematic representation of a biphasic waveform delivered according to the third aspect of this invention.

FIG. 8 is a schematic representation of a biphasic waveform delivered according to the third aspect of this invention.

FIG. 9 is a flow chart demonstrating part of an electrotherapy method according to a combination of the second and third aspects of this invention.

FIG. 10 is a block diagram of a defibrillator system according to a preferred embodiment of this invention.

FIG. 11 is a schematic circuit diagram of a defibrillator system according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGS. 1 and 2 illustrate the patient-to-patient differences that an external defibrillator design must take into account. These figures are schematic representations of truncated exponential biphasic waveforms delivered to two different patients from an external defibrillator according to the electrotherapy method of this invention for defibrillation or cardioversion. In these drawings, the vertical axis is voltage, and the horizontal axis is time. The principles discussed here are applicable to waveforms described in terms of current versus time as well, however.

The waveform shown in FIG. 1 is called a low-tilt waveform, and the waveform shown in FIG. 2 is called a high-tilt waveform, where tilt H is defined as a percent as follows:

$$H = \frac{|A| - |D|}{|A|} \times 100$$

As shown in FIGS. 1 and 2, A is the initial first phase voltage and D is the second phase terminal voltage. The first phase terminal voltage B results from the exponential decay over time of the initial voltage A through the patient, and the second phase terminal voltage D results from the exponential decay of the second phase initial voltage C in the same manner. The starting voltages and first and second phase durations of the FIG. 1 and FIG. 2 waveforms are the same; the differences in end voltages B and D reflect differences in patient impedance.

Prior art disclosures of the use of truncated exponential biphasic waveforms in implantable defibrillators have provided little guidance for the design of an external defibrillator that will achieve acceptable defibrillation or cardioversion rates across a wide population of patients. The defibrillator operating voltages and energy delivery requirements affect the size, cost, weight and availability of components. In particular, operating voltage requirements affect the choice of switch and capacitor technologies. Total

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energy delivery requirements affect defibrillator battery and capacitor choices.

We have determined that, for a given patient, externally-applied truncated exponential biphasic waveforms defibrillate at lower voltages and at lower total delivered energies than externally-applied monophasic waveforms. In addition, we have determined that there is a complex relationship between total pulse duration, first to second phase duration ratio, initial voltage, total energy and total tilt.

Up to a point, the more energy delivered to a patient in an electrotherapeutic pulse, the more likely the defibrillation attempt will succeed. Low-tilt biphasic waveforms achieve effective defibrillation rates with less delivered energy than high-tilt waveforms. However, low-tilt waveforms are energy inefficient, since much of the stored energy is not delivered to the patient. On the other hand, defibrillators delivering high-tilt biphasic waveforms deliver more of the stored energy to the patient than defibrillators delivering low-tilt waveforms while maintaining high efficacy up to a certain critical tilt value. Thus, for a given capacitor, a given initial voltage and fixed phase durations, high impedance patients receive a waveform with less total energy and lower peak currents but better conversion properties per unit of energy delivered, and low impedance patients receive a waveform with more delivered energy and higher peak currents. There appears to be an optimum tilt range in which high and low impedance patients will receive effective and efficient therapy. An optimum capacitor charged to a predetermined voltage can be chosen to deliver an effective and efficient waveform across a population of patients having a variety of physiological differences.

This invention is a defibrillator and defibrillation method that takes advantage of this relationship between waveform tilt and total energy delivered in high and low impedance patients. In one aspect of the invention, the defibrillator operates in an open loop, i.e., without any feedback regarding patient impedance parameters and with preset pulse phase durations. The preset parameters of the waveforms shown in FIGS. 1 and 2 are therefore the initial voltage A of the first phase of the pulse, the duration E of the first phase, the interphase duration G, and the duration F of the second phase. The terminal voltage B of the first phase, the initial voltage C of the second phase, and the terminal voltage D of the second phase are dependent upon the physiological parameters of the patient and the physical connection between the electrodes and the patient.

For example, if the patient impedance (i.e., the total impedance between the two electrodes) is high, the amount of voltage drop (exponential decay) from the initial voltage A to the terminal voltage B during time E will be lower (FIG. 1) than if the patient impedance is low (FIG. 2). The same is true for the initial and terminal voltages of the second phase during time F. The values of A, E, G and F are set to optimize defibrillation and/or cardioversion efficacy across a population of patients. Thus, high impedance patients receive a low-tilt waveform that is more effective per unit of delivered energy, and low impedance patients receive a high-tilt waveform that delivers more of the stored energy and is therefore more energy efficient.

Another feature of biphasic waveforms is that waveforms with relatively longer first phases have better conversion properties than waveforms with equal or shorter first phases, provided the total duration exceeds a critical minimum. Therefore, in the case of high impedance patients, it may be desirable to extend the first phase of the biphasic waveform (while the second phase duration is kept constant) to increase the overall efficacy of the electrotherapy by deliv-

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ering a more efficacious waveform and to increase the total amount of energy delivered. FIGS. 3-5 demonstrate a defibrillation method according to this second aspect of the invention in which information related to patient impedance is fed back to the defibrillator to change the parameters of the delivered electrotherapeutic pulse.

FIG. 3 is a flow chart showing the method steps following the decision (by an operator or by the defibrillator itself) to apply an electrotherapeutic shock to the patient through electrodes attached to the patient and charging of the energy source, e.g., the defibrillator's capacitor or capacitor bank, to the initial first phase voltage A. Block 10 represents initiation of the first phase of the pulse in a first polarity. Discharge may be initiated manually by the user or automatically in response to patient heart activity measurements (e.g., ECG signals) received by the defibrillator through the electrodes and analyzed by the defibrillator controller in a manner known in the art.

Discharge of the first phase continues for at least a threshold time t_{THRESH} , as shown by block 12 of FIG. 3. If, at the end of time t_{THRESH} , the voltage measured across the energy source has not dropped below the minimum first phase terminal voltage threshold V_{THRESH} , first phase discharge continues, as shown in block 14 of FIG. 3. For high impedance patients, this situation results in an extension of the first phase duration beyond t_{THRESH} , as shown in FIG. 4, until the measured voltage drops below the threshold V_{THRESH} . Discharge then ends to complete the first phase, as represented by block 16 of FIG. 3. If, on the other hand, the patient has low impedance, the voltage will have dropped below V_{THRESH} when the time threshold is reached, resulting in a waveform like the one shown in FIG. 5.

At the end of the first phase, and after a predetermined interim period G, the polarity of the energy source connection to the electrodes is switched, as represented by blocks 18 and 20 of FIG. 3. Discharge of the second phase of the biphasic pulse then commences and continues for a predetermined second phase duration F, as represented by block 26 of FIG. 3, then ceases. This compensating electrotherapy method ensures that the energy is delivered by the defibrillator in the most efficacious manner by providing for a minimum waveform tilt and by extending the first phase duration to meet the requirements of a particular patient.

Because this method increases the waveform tilt for high impedance patients and delivers more of the energy from the energy source than a method without compensation, the defibrillator's energy source can be smaller than in prior art external defibrillators, thereby minimizing defibrillator size, weight and expense. It should be noted that the waveforms shown in FIGS. 4 and 5 could be expressed in terms of current versus time using a predetermined current threshold value without departing from the scope of the invention.

FIGS. 6-8 illustrate a third aspect of this invention that prevents the delivered waveform from exceeding a maximum tilt (i.e., maximum delivered energy) in low impedance patients. As shown by blocks 32 and 34 in FIG. 6, the first phase discharge stops either at the end of a predetermined time t_{THRESH} or when the first phase voltage drops below V_{THRESH} . The second phase begins after an interim period G and continues for a preset period F as in the second aspect of the invention. Thus, in high impedance patients, the first phase ends at time t_{THRESH} , even if the voltage has not yet fallen below V_{THRESH} , as shown in FIG. 7. In low impedance patients, on the other hand, the first phase of the delivered waveform could be shorter in duration than the time t_{THRESH} as shown in FIG. 8.

Once again, the waveforms shown in FIGS. 7 and 8 could be expressed in terms of current versus time using a pred-

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termined current threshold value without departing from the scope of the invention.

FIG. 9 is a flow chart illustrating a combination of the defibrillation methods illustrated in FIGS. 3 and 6. In this combination method, the first phase of the biphasic waveform will end if the voltage reaches a first voltage threshold V_{THRESH} prior to the first phase duration threshold t_{THRESH} as shown by blocks 91 and 92. This defibrillator decision path delivers a waveform like that shown in FIG. 8 for low impedance patients. For high impedance patients, on the other hand, if at the expiration of t_{THRESH} the voltage has not fallen below V_{THRESH} , the duration of the first phase is extended beyond t_{THRESH} until the voltage measured across the electrodes reaches a second voltage threshold V_{THRESH} as shown in decision blocks 91 and 93. This defibrillator method path will deliver a waveform like that shown in FIG. 4.

In alternative embodiments of this invention, the second phase pulse could be a function of the first phase voltage, current or time instead of having a fixed time duration. In addition, any of the above embodiments could provide for alternating initial polarities in successive monophasic or biphasic pulses. In other words, if in the first biphasic waveform delivered by the system the first phase is a positive voltage or current pulse followed by a second phase negative voltage or current pulse, the second biphasic waveform delivered by the system would be a negative first phase voltage or current pulse followed by a positive second phase voltage or current pulse. This arrangement would minimize electrode polarization, i.e., build-up of charge on the electrodes.

For each defibrillator method discussed above, the initial first phase voltage A may be the same for all patients or it may be selected automatically or by the defibrillator user. For example, the defibrillator may have a selection of initial voltage settings, one for an infant, a second for an adult, and a third for use in open heart surgery.

FIG. 10 is a schematic block diagram of a defibrillator system according to a preferred embodiment of this invention. The defibrillator system 30 comprises an energy source 32 to provide the voltage or current pulses described above. In one preferred embodiment, energy source 32 is a single capacitor or a capacitor bank arranged to act as a single capacitor. A connecting mechanism 34 selectively connects and disconnects energy source 32 to and from a pair of electrodes 36 electrically attached to a patient, represented here as a resistive load 37. The connections between the electrodes and the energy source may be in either of two polarities with respect to positive and negative terminals on the energy source.

The defibrillator system is controlled by a controller 38. Specifically, controller 38 operates the connecting mechanism 34 to connect energy source 32 with electrodes 36 in one of the two polarities or to disconnect energy source 32 from electrodes 36. Controller 38 receives timing information from a timer 40, and timer 40 receives electrical information from electrical sensor 42 connected across energy source 32. In some preferred embodiments, sensor 42 is a voltage sensor; in other preferred embodiments, sensor 42 is a current sensor.

FIG. 11 is a schematic circuit diagram illustrating a device according to the preferred embodiments discussed above. Defibrillator controller 70 activates a high voltage power supply 72 to charge storage capacitor 74 via diode 76 to a predetermined voltage. During this period, switches SW1, SW2, SW3 and SW4 are turned off so that no voltage is applied to the patient (represented here as resistor 78)

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connected between electrodes 80 and 82. SW5 is turned on during this time.

After charging the capacitor, controller 70 de-activates supply 72 and activates biphasic switch timer 84. Timer 84 initiates discharge of the first phase of the biphasic waveform through the patient in a first polarity by simultaneously turning on switches SW1 and SW4 via control signals T1 and T4, while switch SW5 remains on to deliver the initial voltage A through electrodes 80 and 82 to the patient 78.

Depending on the operating mode, delivery of the first phase of the biphasic pulse may be terminated by the timer 84 after the end of a predetermined period or when the voltage across the electrodes has dropped below a predetermined value as measured by comparator 86. Timer 84 terminates pulse delivery by turning off switch SW5 via control signal T5, followed by turning off switches SW1 and SW4. The voltage across electrodes 80 and 82 then returns to zero.

During the interim period G, SW5 is turned on to prepare for the second phase. After the end of interim period G, timer 84 initiates delivery of the second phase by simultaneously turning on switches SW2 and SW3 via control signals T2 and T3 while switch SW5 remains on. This configuration applies voltage from the capacitor to the electrodes at an initial second phase voltage C and in a polarity opposite to the first polarity. Timer 84 terminates delivery of the second phase by turning off switch SW5 via control signal T5, followed by turning off switches SW2 and SW3. The second phase may be terminated at the end of a predetermined period or when the voltage measured by comparator 86 drops below a second phase termination voltage threshold.

In a preferred embodiment, switch SW5 is an insulated gate bipolar transistor (IGBT) and switches SW1-SW4 are silicon-controlled rectifiers (SCRs). The SCRs are avalanche-type switches which can be turned on to a conductive state by the application of a control signal, but cannot be turned off until the current through the switch falls to zero or near zero. Thus, the five switches can be configured so that any of the switches SW1-SW4 will close when SW5 is closed and will reopen only upon application of a specific control signal to SW5.

This design has the further advantage that switch SW5 does not need to withstand the maximum capacitor voltage. The maximum voltage that will be applied across switch SW5 will occur when the first phase is terminated by turning SW5 off, at which time the capacitor voltage has decayed to some fraction of its initial value.

Other switches and switch configurations may be used, of course without departing from the scope of the invention. In addition, the defibrillator configurations of FIGS. 10 and 11 may be used to deliver electric pulses of any polarity, amplitude, and duration singly and in any combination.

While the invention has been discussed with reference to external defibrillators, one or more aspects of the invention would be applicable to implantable defibrillators as well. Other modifications will be apparent to those skilled in the art.

What is claimed is:

1. An external defibrillator comprising:

an energy source;

first and second electrodes in electrical communication with the exterior of a patient;

a controller controlling application of electrical energy from the energy source to the electrodes, the controller comprising,

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a timer for generating a timing signal corresponding to the application of electrical energy from the energy source to the electrodes, and

means for selectively connecting the energy source to the electrodes in a first polarity and a second polarity.

2. The apparatus of claim 1 wherein the controller further comprises means for measuring an electrical unit of the energy source applied across the electrodes and for generating a signal corresponding to the measured electrical unit.

3. The apparatus of claim 2 wherein the energy source is a voltage source and the measured electrical unit is voltage.

4. The apparatus of claim 3 wherein the voltage source comprises a capacitor.

5. The apparatus of claim 2 wherein the energy source is a current source and the measured electrical unit is current.

6. The apparatus of claim 2 wherein the controller further comprises threshold means for determining whether the measured electrical unit signal is less than a predetermined threshold value.

7. The apparatus of claim 6 wherein the means for selectively connecting comprises a first switch for connecting a first terminal of the energy source with the first electrode; a second switch for connecting the first terminal of the energy source with the second electrode; a third switch for connecting the first electrode with a junction; a fourth switch for connecting the second electrode with the junction; and a fifth switch for connecting the junction with the second terminal of the energy source.

8. An external defibrillator comprising:

an energy source;

first and second electrodes adapted to make contact with a patient;

a plurality of electronic switches;

a controller controlling application of electrical energy from the energy source to the electrodes through the electronic switches in a truncated exponential multiphasic waveform.

9. The external defibrillator of claim 8 wherein the controller further comprises a timer.

10. The external defibrillator of claim 8 further comprising means for limiting voltage applied across one of the plurality of electronic switches.

11. The external defibrillator of claim 10, the plurality of electronic switches comprising:

a first switch coupled between a first terminal of the energy source and the first electrode;

a second switch coupled between the first terminal of the energy source and the second electrode;

a third switch coupled between the first electrode and a second terminal of the energy source;

a fourth switch coupled between the second electrode and the second terminal of the energy source; and

the means for limiting voltage comprising a fifth switch interposed between the second terminal and the third and fourth switches of the energy source; wherein any of the first, second, third and fourth switches may close only when the fifth switch is closed and may re-open only when the fifth switch is open.

12. The external defibrillator of claim 8 wherein the energy source consists of a single capacitor.

* * * * *

Exhibit E





US005607454A

United States Patent [19]
Cameron et al.

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[45] Date of Patent: **Mar. 4, 1997**

[54] **ELECTROTHERAPY METHOD AND APPARATUS**

WO94/21327 9/1994 WIPO.
WO94/22530 10/1994 WIPO.

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[21] Appl. No.: 227,553

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[52] U.S. Cl. 607/5; 607/7; 607/6; 607/74;
607/62

[58] Field of Search 607/2, 4, 5-7,
607/62, 74

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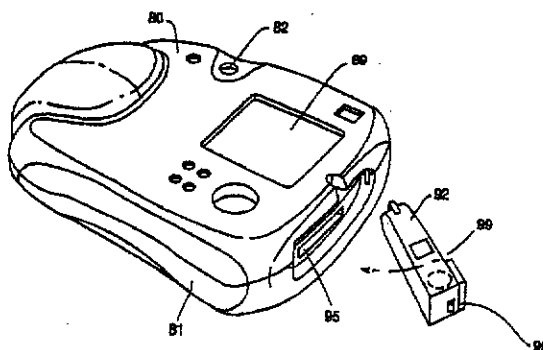
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[57] ABSTRACT

An electrotherapy method and apparatus for delivering a multiphasic waveform from an energy source to a patient. The preferred embodiment of the method comprises the steps of charging the energy source to an initial level; discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform; monitoring a patient-dependent electrical parameter during the discharging step; shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter. The preferred apparatus comprises an energy source; two electrodes adapted to make electrical contact with a patient; a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; and a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy. The preferred defibrillator apparatus weighs less than 4 pounds and has a volume less than 150 cubic inches, and most preferably, weighs approximately three pounds or less and has a volume of approximately 141 cu. in.

59 Claims, 4 Drawing Sheets



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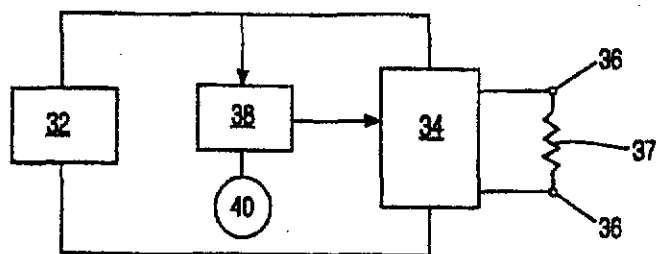
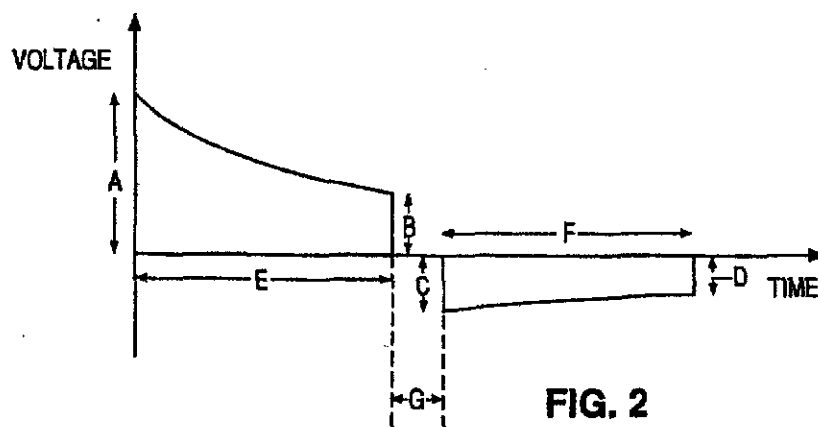
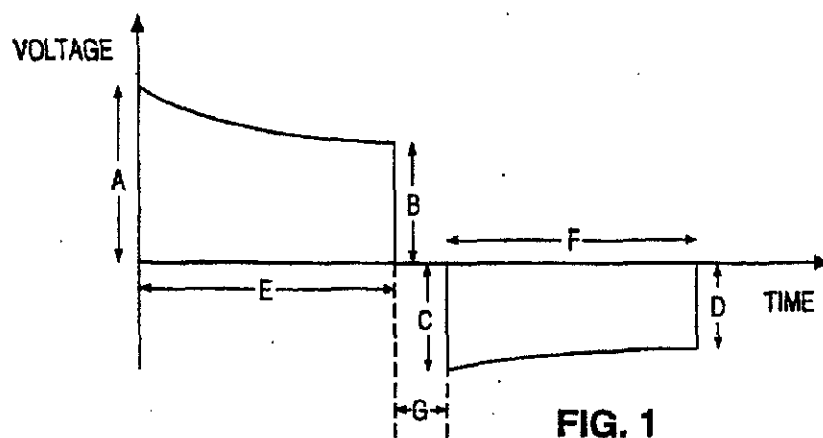
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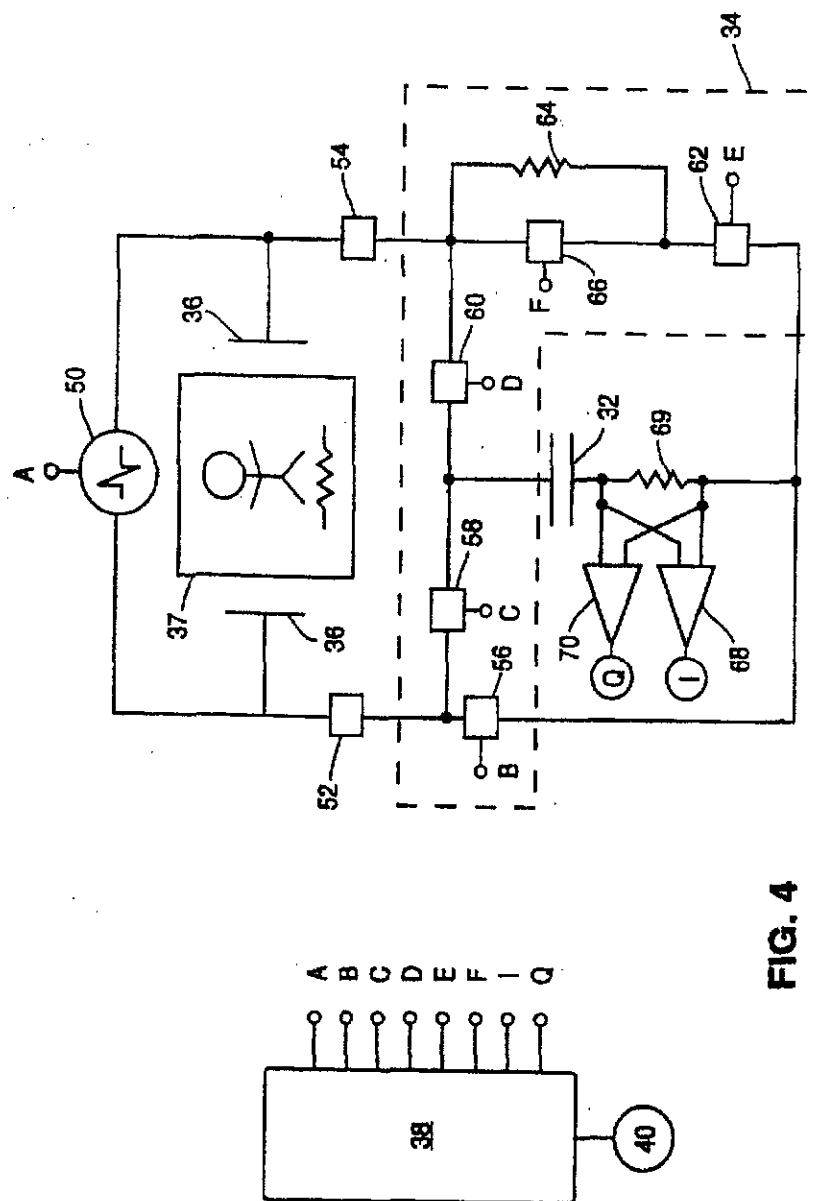


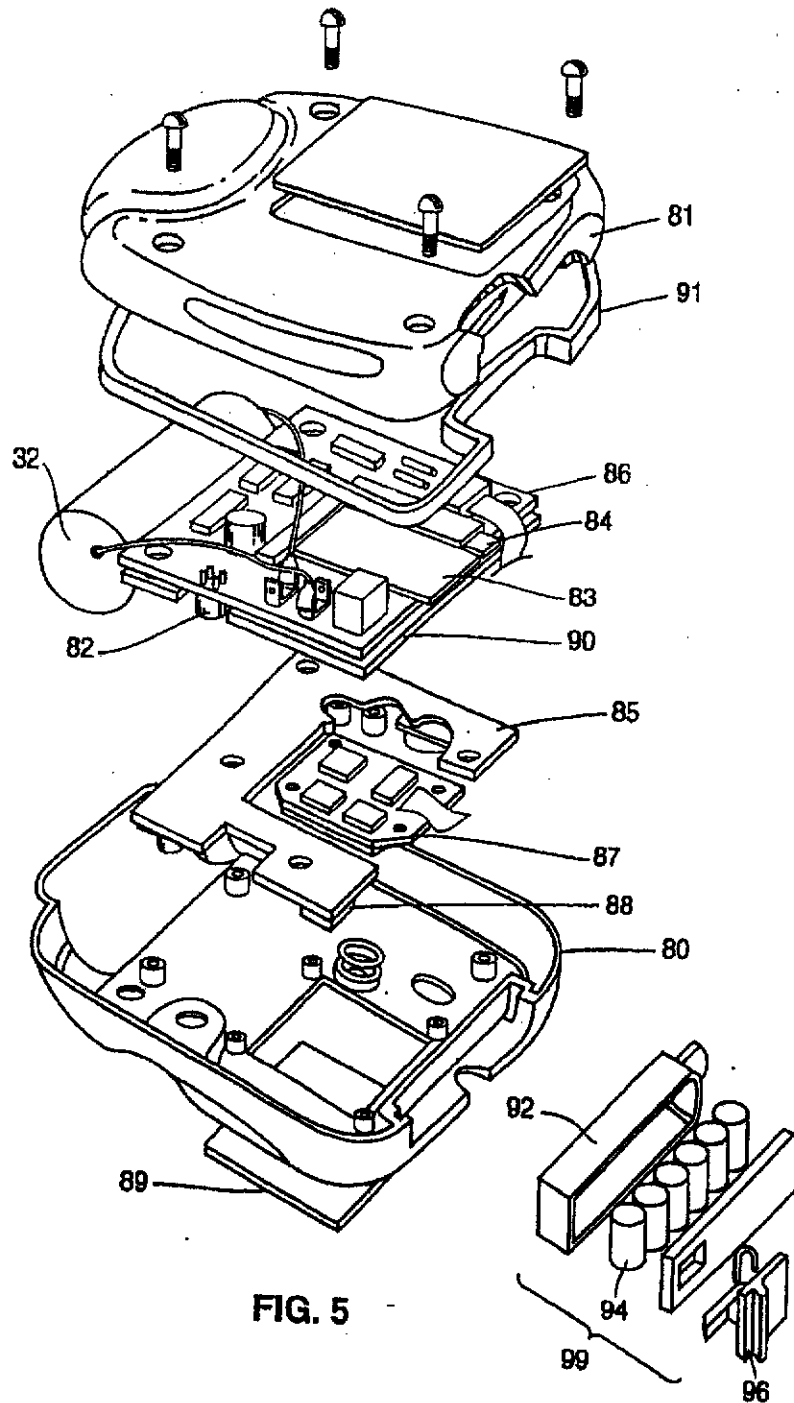
FIG. 4

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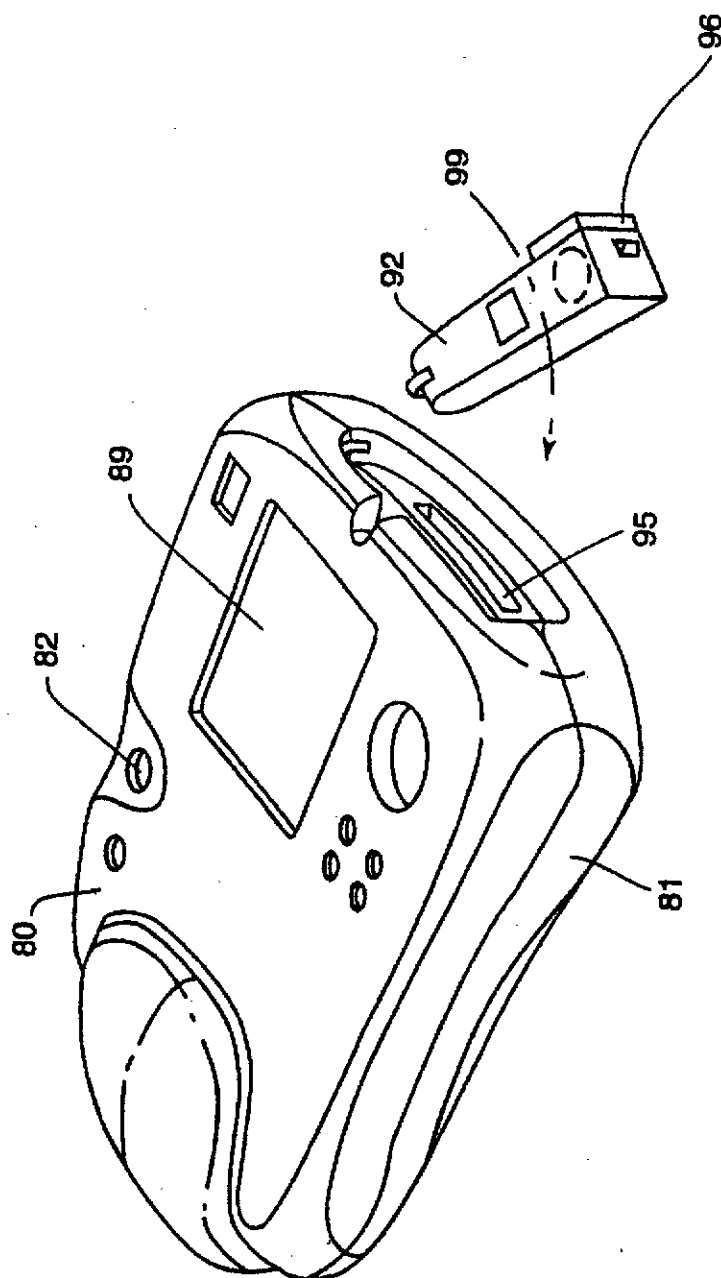


FIG. 6

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ELECTROTHERAPY METHOD AND APPARATUS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. patent application Ser. No. 08/103,837 filed Aug. 6, 1993, the disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates generally to an electrotherapy method and apparatus for delivering an electrical pulse to a patient's heart. In particular, this invention relates to a method and apparatus for shaping the electrical waveform delivered by the defibrillator based on an electrical parameter measured during delivery of the waveform. The invention also relates to a defibrillator design meeting certain threshold size and weight requirements.

Sudden cardiac death is the leading cause of death in the United States. Most sudden cardiac death is caused by ventricular fibrillation, in which the heart's muscle fibers contract without coordination, thereby interrupting normal blood flow to the body. The only effective treatment for ventricular fibrillation is electrical defibrillation, which applies an electrical shock to the patient's heart.

To be effective, the defibrillation shock must be delivered to the patient within minutes of the onset of ventricular fibrillation. Studies have shown that defibrillation shocks delivered within one minute after ventricular fibrillation begins achieve up to 100% survival rate. The survival rate falls to approximately 30% if 6 minutes elapse before the shock is administered. Beyond 12 minutes, the survival rate approaches zero.

One way of delivering rapid defibrillation shocks is through the use of implantable defibrillators. Implantable defibrillators are surgically implanted in patients who have a high likelihood of needing electrotherapy in the future. Implanted defibrillators typically monitor the patient's heart activity and automatically supply electrotherapeutic pulses directly to the patient's heart when indicated. Thus, implanted defibrillators permit the patient to function in a somewhat normal fashion away from the watchful eye of medical personnel. Implantable defibrillators are expensive, however, and are used on only a small fraction of the total population at risk for sudden cardiac death.

External defibrillators send electrical pulses to the patient's heart through electrodes applied to the patient's torso. External defibrillators are useful in the emergency room, the operating room, emergency medical vehicles or other situations where there may be an unanticipated need to provide electrotherapy to a patient on short notice. The advantage of external defibrillators is that they may be used on a patient as needed, then subsequently moved to be used with another patient.

However, because external defibrillators deliver their electrotherapeutic pulses to the patient's heart indirectly (i.e., from the surface of the patient's skin rather than directly to the heart), they must operate at higher energies, voltages and/or currents than implanted defibrillators. These high energy, voltage and current requirements have made existing external defibrillators large, heavy and expensive, particularly due to the large size of the capacitors or other energy storage media required by these prior art devices. The size and weight of prior art external defibrillators have

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limited their utility for rapid response by emergency medical response teams.

Defibrillator waveforms, i.e., time plots of the delivered current or voltage pulses, are characterized according to the shape, polarity, duration and number of pulse phases. Most current external defibrillators deliver monophasic current or voltage electrotherapeutic pulses, although some deliver biphasic sinusoidal pulses. Some prior art implantable defibrillators, on the other hand, use truncated exponential, biphasic waveforms. Examples of biphasic implantable defibrillators may be found in U.S. Pat. No. 4,821,723 to Baker, Jr., et al.; U.S. Pat. No. 5,083,562 to de Coriolis et al.; U.S. Pat. No. 4,800,883 to Winstrom; U.S. Pat. No. 4,850,357 to Bach, Jr.; U.S. Pat. No. 4,953,551 to Mehra et al.; and U.S. Pat. No. 5,230,336 to Fain et al.

Because each implanted defibrillator is dedicated to a single patient, its operating parameters, such as electrical pulse amplitudes and total energy delivered, may be effectively titrated to the physiology of the patient to optimize the defibrillator's effectiveness. Thus, for example, the initial voltage, first phase duration and total pulse duration may be set when the device is implanted to deliver the desired amount of energy or to achieve a desired start and end voltage differential (i.e., a constant tilt). Even when an implanted defibrillator has the ability to change its operating parameters to compensate for changes in the impedance of the defibrillators leads and/or the patient's heart (as discussed in the Fain patent), the range of potential impedance changes for a single implantation in a single patient is relatively small.

In contrast, because external defibrillator electrodes are not in direct contact with the patient's heart, and because external defibrillators must be able to be used on a variety of patients having a variety of physiological differences, external defibrillators must operate according to pulse amplitude and duration parameters that will be effective in most patients, no matter what the patient's physiology. For example, the impedance presented by the tissue between external defibrillator electrodes and the patient's heart varies from patient to patient, thereby varying the intensity and waveform shape of the shock actually delivered to the patient's heart for a given initial pulse amplitude and duration. Pulse amplitudes and durations effective to treat low impedance patients do not necessarily deliver effective and energy efficient treatments to high impedance patients.

External defibrillators may be subjected to extreme load conditions which could potentially damage the waveform generator circuits. For example, improperly applied defibrillator electrodes may create a very low impedance current path during the shock delivery, which could result in excessively high current within the waveform circuit. Thus, an external defibrillator has an additional design requirement to limit the peak current to safe levels in the waveform circuit, which is not normally a concern for implanted defibrillators.

Prior art defibrillators have not fully addressed the patient variability problem. One prior art approach to this problem was to provide an external defibrillator with multiple energy settings that could be selected by the user. A common protocol for using such a defibrillator was to attempt defibrillation at an initial energy setting suitable for defibrillating a patient of average impedance, then raise the energy setting for subsequent defibrillation attempts in the event that the initial setting failed. The repeated defibrillation attempts require additional energy and add to patient risk.

Some prior art defibrillators measure the patient impedance, or a parameter related to patient impedance, and alter

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the shape of a subsequent defibrillation shock based on the earlier measurement. For example, the implanted defibrillator described in the Fain patent delivers a defibrillation shock of predetermined shape to the patient's heart in response to a detected arrhythmia. The Fain device measures the system impedance during delivery of that shock and uses the measured impedance to alter the shape of a subsequently delivered shock.

Another example of the measurement and use of patient impedance information in prior art defibrillators is described in an article written by R. E. Kerber, et al., "Energy, current, and success in defibrillation and cardioversion," *Circulation* (May 1988). The authors describe an external defibrillator that administers a test pulse to the patient prior to administering the defibrillation shock. The test pulse is used to measure patient impedance; the defibrillator adjusts the amount of energy delivered by the shock in response to the measured patient impedance. The shape of the delivered waveform is a damped sinusoid.

Prior art disclosures of the use of truncated exponential biphasic waveforms in implantable defibrillators have provided little guidance for the design of an external defibrillator that will achieve acceptable defibrillation or cardioversion rates across a wide population of patients. The defibrillator operating voltages and energy delivery requirements affect the size, cost, weight and availability of components. In particular, operating voltage requirements affect the choice of switch and capacitor technologies. Total energy delivery requirements affect defibrillator battery and capacitor choices. Thus, even if an implantable defibrillator and an external defibrillator both deliver waveforms of similar shape, albeit with different waveform amplitudes, the actual designs of the two defibrillators would be radically different.

SUMMARY OF THE INVENTION

This invention provides a defibrillator and defibrillation method that automatically compensates for patient-to-patient differences in the delivery of electrotherapeutic pulses for defibrillation and cardioversion. The defibrillator has an energy source that may be discharged through electrodes to administer a truncated exponential biphasic voltage or current pulse to a patient.

The preferred embodiment of the method comprises the steps of charging the energy source to an initial level; discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform; monitoring a patient-dependent electrical parameter during the discharging step; shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter.

The preferred apparatus comprises an energy source; two electrodes adapted to make electrical contact with a patient; a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; and a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy. The preferred defibrillator apparatus weighs less than 4 pounds and has a volume less than 150 cubic inches, and most preferably, weighs approximately three pounds or less and has a volume of approximately 141 cu. in.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic representation of a low-tilt biphasic electrotherapeutic waveform.

FIG. 2 is a schematic representation of a high-tilt biphasic electrotherapeutic waveform.

FIG. 3 is a block diagram of a defibrillator system according to a preferred embodiment of the invention.

FIG. 4 is a schematic circuit diagram of a defibrillator system according to a preferred embodiment of this invention.

FIG. 5 is an external view of a defibrillator according to a preferred embodiment of this invention.

FIG. 6 is a partial cutaway view of a defibrillator according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

For any given patient and for any given defibrillator system design, whether implantable or external, there is an optimal biphasic waveform for treating a particular kind of arrhythmia. This principle is used when implanting defibrillators; as noted above, implanted defibrillators are titrated to the patient at the time of implant. External defibrillators, on the other hand, must be designed to be effective in a wide population of patients.

For example, FIGS. 1 and 2 illustrate the patient-to-patient differences that an external defibrillator design must take into account. These figures are schematic representations of truncated exponential biphasic waveforms delivered to two different patients from an external defibrillator according to the electrotherapy method of this invention for defibrillation or cardioversion. In these drawings, the vertical axis is voltage, and the horizontal axis is time. The principles discussed here are applicable to waveforms described in terms of current versus time as well.

The waveform shown in FIG. 1 is called a low-tilt waveform, and the waveform shown in FIG. 2 is called a high-tilt waveform, where tilt H is defined as a percent as follows:

$$H = \frac{|A| - |D|}{|A|} \times 100$$

As shown in FIGS. 1 and 2, A is the initial first phase voltage and D is the second phase terminal voltage. The first phase terminal voltage B results from the exponential decay over time of the initial voltage A through the patient, and the second phase terminal voltage D results from the exponential decay of the second phase initial voltage C in the same manner. The starting voltages and first and second phase durations of the FIG. 1 and FIG. 2 waveforms are the same; the differences in end voltages B and D reflect patient differences.

We have determined that, for a given patient, externally-applied truncated exponential biphasic waveforms defibrillate at lower voltages and at lower total delivered energies than externally-applied monophasic waveforms. In addition, we have determined that there is a complex relationship between total pulse duration, first to second phase duration ratio, initial voltage, total energy and total tilt in the delivery of an effective cardioversion waveform. Thus, it is possible to design a defibrillator and defibrillation method that is effective not only for a single patient (as in most prior art implantable defibrillators) but is also effective for a broad

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population of patients. In addition, it is also possible to meet external defibrillator design requirements regarding the size, weight and capacity of the defibrillator energy source while still meeting the needs of a wide patient population.

Up to a point, the more energy delivered to a patient in an electrotherapeutic pulse, the more likely the defibrillation attempt will succeed. Low-tilt biphasic waveforms achieve effective defibrillation rates with less delivered energy than high-tilt waveforms. However, low-tilt waveforms are energy inefficient, since much of the stored energy is not delivered to the patient. On the other hand, defibrillators delivering high-tilt biphasic waveforms deliver more of the stored energy to the patient than defibrillators delivering low-tilt waveforms while maintaining high efficacy up to a certain critical tilt value. Thus, for a given capacitor, a given initial voltage and fixed phase durations, high impedance patients receive a waveform with less total energy and lower peak currents but better conversion properties per unit of energy delivered, and low impedance patients receive a waveform with more delivered energy and higher peak currents.

There appears to be an optimum tilt range in which high and low impedance patients will receive effective and efficient therapy from an external defibrillator. An optimum capacitor charged to a predetermined voltage can be chosen to deliver an effective and efficient waveform across a population of patients having a variety of physiological differences. For example, the defibrillator may operate in an open loop, i.e., without any feedback regarding patient parameters and with preset pulse phase durations which will be effective for a certain range of patients. The preset parameters of the waveforms shown in FIG. 1 and 2 are therefore the initial voltage A of the first phase of the pulse, the duration E of the first phase, the interphase duration G, and the duration F of the second phase. The terminal voltage B of the first phase, the initial voltage C of the second phase, and the terminal voltage D of the second phase are dependent upon the physiological parameters of the patient and the physical connection between the electrodes and the patient.

For example, if the patient impedance (i.e., the total impedance between the two electrodes) is high, the amount of voltage drop (exponential decay) from the initial voltage A to the terminal voltage B during time E will be lower (FIG. 1) than if the patient impedance is low (FIG. 2). The same is true for the initial and terminal voltages of the second phase during time F. The values of A, E, G and F are set to optimize defibrillation and/or cardioversion efficacy across a population of patients. Thus, high impedance patients receive a low-tilt waveform that is more effective per unit of delivered energy, and low impedance patients receive a high-tilt waveform that delivers more of the stored energy and is therefore more energy efficient.

In order to ensure that the delivered shock will be within the optimum tilt range for an extended range of patients, this invention provides a defibrillator method and apparatus for adjusting the characteristics of the defibrillator waveform in response to a real-time measurement of a patient-dependent electrical parameter. FIG. 3 is a block diagram showing a preferred embodiment of the defibrillator system.

The defibrillator system 30 comprises an energy source 32 to provide a voltage or current pulse. In one preferred embodiment, energy source 32 is a single capacitor or a capacitor bank arranged to act as a single capacitor.

A connecting mechanism 34 selectively connects and disconnects a pair of electrodes 36 electrically attached to a patient (represented here as a resistive load 37) to and from the energy source. The connections between the electrodes

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and the energy source may be in either of two polarities with respect to positive and negative terminals on the energy source.

The defibrillator system is controlled by a controller 38. Specifically, controller 38 operates the connecting mechanism 34 to connect energy source 32 with electrodes 36 in one of the two polarities or to disconnect energy source 32 from electrodes 36. Controller 38 receives discharge information (such as current, charge and/or voltage) from the discharge circuit. Controller 38 may also receive timing information from a timer 40.

Controller 38 uses information from the discharge circuit and/or the timer to control the shape of the waveform delivered to the patient in real time (i.e., during delivery of the waveform), such as by selecting appropriate waveform parameters from a memory location associated with the controller or by otherwise adjusting the duration of the phases of the biphasic waveform. By controlling the waveform shape, the system controls the duration, tilt and total delivered energy of the waveform. For example, biphasic waveforms with relatively longer first phases have better conversion properties than waveforms with equal or shorter first phases, provided the total duration exceeds a critical minimum. Therefore, in the case of high impedance patients, it may be desirable to increase the duration of the first phase of the biphasic waveform relative to the duration of the second phase to increase the overall efficacy of the electrotherapy by delivering a more efficacious waveform and to increase the total amount of energy delivered.

A preferred embodiment of a defibrillator system according to the invention is shown schematically in FIG. 4. In this diagram, the energy source is a capacitor 32 preferably having a size between 60 and 150 microfarads, most preferably 100 microfarads. The system also includes a charging mechanism (not shown) for charging the capacitor to an initial voltage.

A controller 38 controls the operation of the defibrillator to deliver a shock to the patient 37 through electrodes 36 automatically in response to a detected arrhythmia or manually in response to a human operator. FIG. 4 shows an ECG system 50 attached to the electrodes to provide ECG monitoring and/or arrhythmia detection. FIG. 4 also shows a pair of switches 52 and 54 isolating the patient and the ECG system from the defibrillation circuitry. Switches 52 and 54 may be any suitable kind of isolators, such as mechanical relays, solid state devices, spark gaps, or other gas discharge devices. The ECG system and the isolation switches are not essential parts of this invention.

In this embodiment, the connecting mechanism 34 includes four switches 56, 58, 60 and 62 operated by the controller 38 to deliver a shock from the energy source 32 to the patient. The preferred embodiment also may include an optional current limiting circuit comprising a resistor 64 and switch 66 to provide additional protection to the defibrillator circuit components and to the defibrillator operator. The operation of the isolation switches and the connecting mechanism to deliver a waveform to the patient is described below.

For purposes of this description, it is assumed that all switches are open prior to discharge. It should be understood that this need not be the case. For example, switches 56, 62 and 66 could start out in the closed position, with the operating sequence of the switches modified accordingly.

In response to a request for a shock, the controller first closes switches 52 and 54, then switch 62, then switch 58 to initiate delivery of a limited shock to the patient. A current sensor 68 monitors the current delivered by the capacitor. If

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the peak current is below a circuit safety threshold, then switch 66 is closed to take safety resistor 64 out of the circuit. Peak current values above the threshold could indicate a short circuit condition.

In the preferred embodiment, the duration of the first and second phases of the biphasic waveform are determined by measuring a patient-dependent electrical parameter. As described in more detail below, the measured parameter in the preferred embodiment is the time it takes for a predetermined amount of charge to be delivered by the energy source to the patient. Charge control can provide better noise immunity than other waveform monitoring methods, such as voltage or current monitoring.

The system shown in FIG. 4 uses a current integrator 70 to provide charge information to the controller. The controller sets the duration of the first and second waveform phases (thereby controlling the waveform shape) based on charge information from current integrator 70. Other means of determining phase durations may be used, of course, without departing from the scope of the invention.

At the end of the first phase of the waveform, the controller opens switch 62 to terminate delivery of the shock. Switch 66 may also be opened at any time from this point on. The controller opens switch 58 as well.

After the lapse of a brief interphase period, the controller closes switches 56 and 60 to initiate delivery of the second phase of the waveform. In the preferred embodiment the second phase duration is determined by the first phase duration. Other means of determining second phase duration are within the scope of the invention, however. At the end of the second phase, the controller opens switch 56 to terminate delivery of the shock. Switches 60, 52 and 54 are opened thereafter.

The following example illustrates a specific implementation of the method and apparatus of this invention. The invention is not limited to the values and circuit elements discussed in this example.

In this example, switches 52 and 54 are implemented as a double pole, double throw mechanical relay. Switches 58 and 60 are each implemented as a pair of SCR's in series in order to meet required standoff voltages with currently available components. Switch 56 is implemented as two insulated gate bipolar transistors ("IGBT's") in series, again due to high voltage requirements.

The functions of switches 66 and 62 are shared among three IGBT's to meet voltage standoff requirements, with one IGBT being on at the same time as switch 66 and off at the same time as switch 62. In this implementation resistor 64 is split into two resistors to equally divide the voltage across the IGBT's.

The current sensor 68 may be used to send current information to the controller for purposes of, e.g., short circuit protection, leads off detection, etc. The manner in which the short circuit or leads off conditions are detected are beyond the scope of this invention. The integrator 70 and current sensor 68 may each be an op-amp feeding a threshold comparator for detecting charge and Current limits, respectively. The integrator could be provided with a switch for resetting to initial conditions prior to a waveform delivery.

A comparator associated with the current integrator monitors the charge delivered to the patient and sends a signal to the waveform controller when the charge reaches 0.06182 Coulombs (referred to as "Qt"). The time required to reach that charge ("t(Qt)") is monitored by the controller using an up/down counter which counts a scaled down reference frequency. One element of the frequency scaler is a select-

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able 2:3 prescaler. The pre-scaler is set to 3 during the first phase. In this example, eleven time thresholds are stored in the controller, which determines the first phase duration ("t(Φ1)") based on the time required to reach Qt. At each time threshold, a new value of t(Φ1) is loaded until Qt is reached. If Qt is not reached within 6.35 mS, then t(Φ1) is set to 12 mS. The counter runs at the scaled down frequency during delivery of the entire first phase.

Some exemplary values for Qt thresholds and t(Φ1) are shown in Table I.

TABLE I

If: t(Qt) < (mS)	Then t(Φ1) is (mS)
1.13	2.3
1.60	2.85
2.07	3.79
2.56	4.02
3.07	4.83
3.58	6.76
4.10	7.73
4.64	8.69
5.20	9.66
5.77	10.62
6.35	11.59

In this example, the interphase delay is set at 300 μS. At 0 μS the first phase IGBT's are opened, terminating the first phase. At 250 μS, the second phase IGBT's are closed. At 300 μS the second phase SCR's are closed, initiating the second phase.

In this example, second phase timing is determined by first phase timing. Specifically, the count value accumulated during phase one (2.3 mS to 12 mS) is used to control the duration of the second phase. During the second phase, the counter that had been counted up during the first phase is counted down to 0, at which time the second phase is terminated. The actual duration of the second phase depends on the scaled down frequency used to run down the counter. If the first phase t(Qt) was less than 3.07 mS, then the reference clock prescaler is set to 3 to give second phase duration equal to the first phase duration. If t(Qt) is greater than or equal to 3.07 mS, then the pre-scaler is set to 2, giving a second phase duration which is ½ of the first phase duration.

In an alternative embodiment, the measured patient-dependent electrical parameter is capacitor voltage. A comparator monitors the capacitor voltage and sends a signal to the waveform controller when the voltage decays to 1000 volts (Vt). As in the charge control embodiment, the time required to reach that voltage is monitored by the controller using an up/down counter which counts a scaled down reference frequency. The first phase duration (t(Φ1)) is based on the time required to reach Vt. The method of selecting the appropriate t(Φ1) is identical to the charge control embodiment. If Vt is not reached within 6.18 mS, then t(Φ1) is set to 12 mS. Table II shows the t(Vt) thresholds and their associated t(Φ1).

TABLE II

If: t(Vt) < (mS)	Then t(Φ1) is (mS)
1.24	2.3
1.73	2.85
2.23	3.79
2.72	4.02
3.22	4.83
3.71	6.76
4.20	7.73

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TABLE II-continued

If $t(V_0) < (mS)$	Then $t(\phi_1)$ is (mS)
4.70	8.69
5.19	9.66
5.69	10.62
6.18	11.59

Interphase delay and second phase timing is identical to the charge control method.

We have designed a new defibrillator meeting certain size, weight, efficacy and safety design goals. The size and weight are below the design thresholds of 150 cu. in. and four lbs. This new portable defibrillator may therefore be carried and stored in places such as drug kit boxes carried by early medical responders and in the glove boxes of cars.

The circuit design of the new defibrillator permits the use of a biphasic truncated exponential waveform, such as one of the waveforms described above. Use of the biphasic waveform permits the defibrillator to be operated with the same efficacy as prior art external defibrillators but with the storage and delivery of far less energy at lower voltages. For example, the new defibrillator effectively cardioverts patients by delivering shocks below 155 Joules of energy (167 Joules of energy stored), and most preferably on the order of 130 Joules of energy (140 Joules stored), compared with the delivery of 200-360 Joules (240-439 Joules stored) by prior art external defibrillators.

A preferred embodiment of the new external defibrillator is shown in FIGS. 5 and 6. This defibrillator is much smaller and lighter than prior art external defibrillators. The size of the preferred defibrillator (approx. 2.2 in. x 8 in. x 8 in., for a total volume of approx. 141 cu. in.) permits it to be carried and/or stored in places in which prior art external defibrillators could not fit. In addition, its lighter weight (approx. three pounds) enables the defibrillator to be moved more easily by the operator in an emergency.

As shown in FIGS. 5 and 6, the preferred external defibrillator includes a molded two-part plastic housing with an upper case 80 and a lower case 81. A main printed circuit board ("PCB") 86 supports the capacitor 32, an electrode connector 82, a PCMCIA memory card 83 and a PCMCIA memory card ejector mechanism 84. The PCMCIA memory card 83 lies within a PCMCIA memory card slot 95 on PCB 86.

A keyboard PCB 85 and a display PCB 87 is disposed between the main PCB 86 and the upper case 80. Keyboard PCB 85 interfaces with the defibrillator's operator buttons, and display PCB 87 operates the defibrillator's LCD display 88. A display window 89 in the upper case permits display 88 to be seen by an operator.

An insulator 90 is disposed between main PCB 86 and display PCB 87. A sealing gasket 91 lines the edges between upper case 80 and lower case 81 when the housing is assembled.

A battery assembly 99 consisting of a battery housing 92 and six lithium-manganese dioxide primary cells 94 is disposed in upper case 80 so that the batteries are in electrical contact with the capacitor charge circuits and other circuits of main PCB 86. The battery assembly has a latching mechanism 96 for attaching and detaching the battery assembly to and from the defibrillator.

The location of the battery assembly in front of the PCMCIA memory card slot prevents the defibrillator operator or others from accessing the PCMCIA card while the defibrillator is powered up and operating. This arrangement protects the operator and patient from accidental shocks and

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protects the defibrillator itself from damage caused by inadvertent removal of the PCMCIA card during operation.

The small size and light weight of our defibrillator is due to a combination of a variety of design features. Use of a truncated exponential biphasic waveform instead of the prior art damped sinusoid waveform permits operation without an inductor in the waveform circuit. In addition, the lower energy requirements permit the use of a smaller capacitor and smaller batteries than those used in prior art external defibrillators.

In an effort to reduce the battery size even further, the preferred embodiment is provided with a capacitor precharge circuit and controller that begins charging the capacitor soon after the defibrillator is activated, even before ventricular fibrillation (and therefore the need for defibrillation) has been detected. The precharge voltage level is kept below the level where damage to the defibrillator circuit, the patient or the operator could occur in the event of a single fault. Thus, for example, whereas in the preferred embodiment the full preshock capacitor voltage is 1650 V, the precharge level is 1100 V. This precharge procedure minimizes the amount of energy that needs to be transferred from the battery to the capacitor when a therapeutic shock is indicated, thereby reducing the required size of the battery and the defibrillator's transformer.

The preferred embodiment uses 6 lithium-manganese dioxide primary cells instead of rechargeable batteries. Primary cells have greater energy density than rechargeable batteries and are cheaper, lighter and, since they are disposable, they are easier to maintain. While primary cells also have lower power and energy characteristics, use of a truncated exponential biphasic waveform and a capacitor precharge circuit permits operation at lower power levels.

The preferred defibrillator shown in FIGS. 5 and 6 incorporates the solid state defibrillator circuit described above with reference to FIG. 4. Use of this circuit along with the short-circuit protection feature described above also reduces the size and weight of the defibrillator by avoiding the use of the mechanical switches required by higher voltage devices.

Other smaller and lighter-weight features of the defibrillator shown in FIGS. 5 and 6 are the use of a flat panel LCD in place of the more conventional CRT display and the use of a PCMCIA memory card to record voice and instrument information instead of a magnetic tape recorder or a paper strip chart recorder. In addition, the preferred defibrillator includes a feature whereby part of the patient ECG information stored within the PCMCIA card can be displayed on the LCD for use by a medical professional. This feature takes the place of the strip chart recorders in prior art external defibrillators.

Lightweight defibrillator electrode designs may be used to reduce the weight of the overall device even further. For example, flexible patch electrodes may be used in place of the conventional paddle electrodes. In addition, because of the lower energy and voltage features of the defibrillator, relatively thin wires may be used to attach the electrodes to the defibrillator instead of thick cables.

Other component choices and other configurations of components are within the scope of this invention as long as the threshold size and weight requirements of 150 cu. in. and four pounds are met.

Any embodiment of this invention could provide for alternating initial polarities in successive monophasic or biphasic pulses. In other words, if in the first biphasic waveform delivered by the system the first phase is a positive voltage or current pulse followed by a second phase

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negative voltage or current pulse, the second biphasic waveform delivered by the system would be a negative first phase voltage or current pulse followed by a positive second phase voltage or current pulse. This arrangement would minimize electrode polarization, i.e., build-up of charge on the electrodes.

For each defibrillator method discussed above, the initial first phase voltage may be the same for all patients or it may be selected automatically or by the defibrillator user. For example, the defibrillator may have a selection of initial voltage settings, one for an infant, a second for an adult, and a third for use in open heart surgery.

In addition, while the preferred embodiment of the invention has been discussed in the context of biphasic waveforms, monophasic, triphasic or other multiphasic waveforms may be used as well. Also, patient-dependent electrical parameters other than charge delivered may be monitored and used to shape the waveform during discharge.

While the invention has been discussed with reference to external defibrillators, one or more aspects of the invention would be applicable to implantable defibrillators as well. Other modifications will be apparent to those skilled in the art.

We claim:

1. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a multiphasic waveform;

monitoring a patient-dependent electrical parameter during the discharging step;

shaping the waveform of the delivered electrical energy based on a value of the monitored electrical parameter, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the monitored electrical parameter.

2. The method of claim 1 wherein the energy source is external to the patient.

3. The method of claim 1 wherein the shaping step further comprises controlling the duration of a waveform phase based on a value of the electrical parameter.

4. The method of claim 3 wherein the shaping step further comprises controlling the duration of another phase of the waveform based on the value.

5. The method of claim 4 further comprising the step of providing a plurality of phase duration values, the shaping step comprising the step of selecting phase duration values for each phase of the multiphasic waveform from the plurality of phase duration values.

6. The method of claim 3 wherein the electrical parameter is charge delivered by the energy source to one of the electrodes.

7. The method of claim 6 wherein the discharging step begins at a discharge start time, the method further comprising the step of monitoring elapsed time from the discharge start time, the shaping step further comprising the step of determining an elapsed time value at which the charge delivered has reached a predetermined threshold.

8. The method of claim 7 wherein the shaping step further comprises selecting a first phase duration based on the elapsed time value.

9. The method of claim 8 wherein the shaping step further comprises selecting a second phase duration based on the elapsed time value.

10. The method of claim 9 wherein the second phase duration is equal to the first phase duration for at least one possible elapsed time value.

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11. The method of claim 9 wherein the second phase duration is less than the first phase duration for at least one possible elapsed time value.

12. The method of claim 1 wherein the duration of the monitoring step is shorter than the duration of the discharging step.

13. The method of claim 1 wherein the shaping step is performed without the use of an inductor.

14. The method of claim 1 wherein the initial level is an initial discharge level, the method further comprising the step of precharging the energy source to a level less than the initial discharge level prior to the step of charging the energy source to the initial discharge level.

15. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform;

monitoring an electrical parameter during the discharging step;

adjusting the tilt of the waveform based on the value of the monitored electrical parameter, the adjusting step comprising controlling the duration of a waveform phase based on a value of the electrical parameter wherein the relative duration of the phases of the waveform is dependent on the value of the monitored electrical parameter.

16. An apparatus for administering electrotherapy to a patient's heart through electrodes external to the patient comprising:

an energy source;

two electrodes adapted to make electrical contact with a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient; an electrical parameter monitor; and

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes in a truncated exponential multiphasic waveform the relative phase durations of which are based on an electrical parameter monitored during delivery of the electrical energy.

17. The apparatus of claim 16 wherein the connecting mechanism comprises a plurality of switches for selectively directing electrical energy from the energy source to the patient in one of two polarities.

18. The apparatus of claim 17 wherein the electrical parameter monitor comprises a charge sensor providing information to the controller related to charge delivered by the energy source to the electrodes.

19. The apparatus of claim 18 further comprising a timer associated with the charge sensor and the controller.

20. The apparatus of claim 19 wherein the controller comprises a counter with a controllable counting rate, the counter being adapted to count in one direction during delivery of a first phase of the multiphasic waveform and in another direction during delivery of a second phase of the multiphasic waveform.

21. The apparatus of claim 16 further comprising means for selectively limiting current flow through the electrodes and means for determining whether current flowing to the electrodes is below a predetermined threshold.

22. The apparatus of claim 21 wherein the means for selectively limiting current flow comprises an impedance

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and a shunting switch in the circuit with the electrodes and the energy source.

23. The apparatus of claim 16 wherein the energy source comprises a battery disposed in a battery holder, the apparatus further comprising a solid state memory device disposed in a memory device holder, the battery blocking external access to the memory device when the battery is disposed in the battery holder.

24. An external defibrillator comprising:

an energy source;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient;

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes; and

a housing containing at least the energy source, the connecting mechanism and the controller, the housing having a volume less than 150 cubic inches.

25. The defibrillator of claim 24 in which the housing has a first dimension not greater than 2.2 inches.

26. The defibrillator of claim 25 in which the housing has second and third dimensions not greater than 8 inches.

27. The defibrillator of claim 24 wherein the energy source comprises primary cell batteries.

28. The defibrillator of claim 27 wherein the primary cell batteries comprise lithium-manganese dioxide primary batteries.

29. The defibrillator of claim 24 wherein the connecting mechanism and the controller comprise means for delivering a multiphasic waveform without the use of an inductor.

30. The defibrillator of claim 24 wherein the energy source comprises a capacitor, the defibrillator further comprising a capacitor precharge circuit.

31. The defibrillator of claim 24 further comprising an ECG system.

32. The defibrillator of claim 31 further comprising an LCD display.

33. The defibrillator of claim 32 further comprising a PCMCIA memory card.

34. The defibrillator of claim 33 further comprising means for displaying ECG information stored in the PCMCIA card on the LCD display.

35. The defibrillator of claim 24 wherein the energy source comprises a capacitive energy source sized between 60 and 150 microfarads.

36. An external defibrillator comprising:

an energy source;

two electrodes adapted to make electrical contact with the exterior of a patient;

a connecting mechanism forming an electrical circuit with the energy source and the electrodes when the electrodes are attached to a patient;

a controller operating the connecting mechanism to deliver electrical energy from the energy source to the electrodes;

the defibrillator having a weight less than four pounds.

37. The defibrillator of claim 36 wherein the energy source comprises primary cell batteries.

38. The defibrillator of claim 37 wherein the primary cell batteries comprise lithium-manganese dioxide primary batteries.

39. The defibrillator of claim 36 wherein the connecting mechanism and the controller comprise means for delivering a multiphasic waveform without the use of an inductor.

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40. The defibrillator of claim 36 wherein the energy source comprises a capacitor, the defibrillator further comprising a capacitor precharge circuit.

41. The defibrillator of claim 36 further comprising an ECG system.

42. The defibrillator of claim 41 further comprising an LCD display.

43. The defibrillator of claim 42 further comprising a PCMCIA memory card.

44. The defibrillator of claim 43 further comprising means for displaying ECG information stored in the PCMCIA card on the LCD display.

45. The defibrillator of claim 36 wherein the energy source comprises a capacitive energy source sized between 60 and 150 microfarads.

46. A method for applying electrotherapy to a patient from an energy source external to the patient, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source to deliver electrical energy to the patient in a multiphasic waveform;

determining the time during which a predetermined amount of charge is delivered to the patient;

shaping the waveform of the delivered electrical energy based on the value of the determined time, wherein the relative duration of the phases of the multiphasic waveform is dependent on the value of the determined time.

47. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

maintaining the charge of the energy source at the initial level;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient.

48. The method of claim 47 wherein the initial level is below a charge level that could harm a patient.

49. The method of claim 47 wherein the first charging step is performed in response to activation of a defibrillator.

50. The method of claim 47 wherein the discharging step comprises the step of discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform.

51. A method for applying electrotherapy to a patient through electrodes connected to an energy source, the method comprising the following steps:

charging the energy source to an initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a waveform, the patient and an additional impedance forming an electrical circuit with the energy source;

monitoring an electrical parameter during the discharging step;

removing the additional impedance from the electrical circuit if the electrical parameter is within a defined range prior to the end of the discharging step.

52. The method of claim 51 wherein the removing step comprises operating a switch associated with the additional impedance.

53. A method for applying electrotherapy to a patient comprising the following steps:

discharging an energy source across electrodes to deliver a waveform of electrical energy to the patient;

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monitoring a patient-dependent electrical parameter during the discharge step;

ceasing the monitoring step prior to the end of the discharge step;

adjusting a waveform discharge parameter based on a value of the monitored parameter. ⁵

54. The method of claim 53 wherein discharging step and the monitoring step begin substantially simultaneously.

55. The method of claim 53 wherein the monitored parameter is time for delivering a predetermined quantity of charge to the patient. ¹⁰

56. The method of claim 55 wherein the discharge parameter is waveform duration.

57. The method of claim 55 wherein the waveform is a biphasic waveform and the discharge parameter is duration of a waveform phase. ¹⁵

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58. A method for applying electrotherapy to a patient through electrodes attached to an energy source, the method comprising the following steps:

charging the energy source to an initial level prior to detecting a need to apply a shock to a patient;

determining the need to apply a shock to a patient;

charging the energy source to a second level greater than the initial level;

discharging the energy source across the electrodes to deliver electrical energy to the patient in a truncated exponential biphasic waveform.

59. The method of claim 58 wherein the first charging step is performed in response to activation of a defibrillator.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,607,454

DATED : March 4, 1997

INVENTOR(S) : David Cameron, Thomas D. Lyster, Daniel J. Powers,
Bradford E. Gliner, Clinton S. Cole, Carlton B. Morgan

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby
corrected as shown below:

On the title page: Item [56]

add to U.S. documents the following:

—5,411,526	5/1995	Kroll et al.	607/5
5,334,430	9/1994	Berg et al.	607/7
5,097,833	3/1992	Campos	607/46 —

Signed and Sealed this
Eleventh Day of November, 1997

Attest:



BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks



US005591213A

United States Patent [19]**Morgan**[11] **Patent Number:** **5,591,213**[45] **Date of Patent:** **Jan. 7, 1997**[54] **DEFIBRILLATOR SYSTEM CONDITION INDICATOR**[75] **Inventor:** **Carlton B. Morgan, Bainbridge Island, Wash.**[73] **Assignee:** **Heartstream, Inc., Seattle, Wash.**[21] **Appl. No.:** **532,863**[22] **Filed:** **Sep. 21, 1995****Related U.S. Application Data**

[63] Continuation of Ser. No. 63,631, May 18, 1993, abandoned.

[51] **Int. Cl.:** **A61N 1/39**[52] **U.S. Cl.:** **607/5**[58] **Field of Search:** **607/4-9, 27, 28, 607/6, 63**[56] **References Cited****U.S. PATENT DOCUMENTS**

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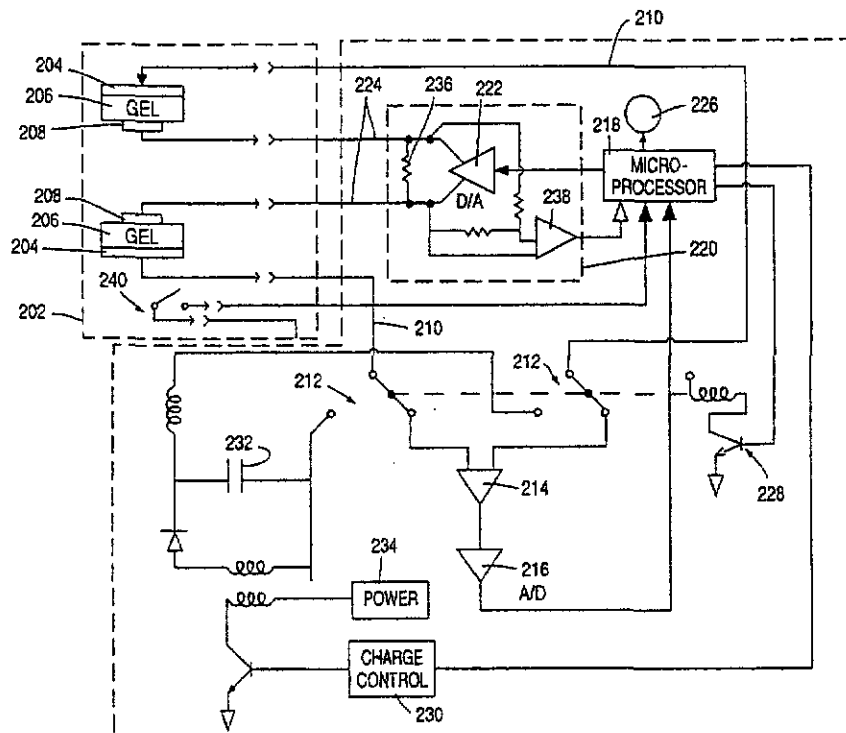
9316759 of 0000 WIPO . 607/5

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Primary Examiner—William E. Kamm*Attorney, Agent, or Firm*—Morrison & Foerster[57] **ABSTRACT**

A defibrillator and electrode system that gives the user a visible and/or audible indication of the condition of the electrodes and other parts of the defibrillator system prior to deployment of the electrodes and use of the defibrillator. In a preferred embodiment of the method of this invention, a patient simulation and analyze circuit within the defibrillator periodically tests the condition of the system and provides the user with a visual indication of the system's condition.

32 Claims, 6 Drawing Sheets

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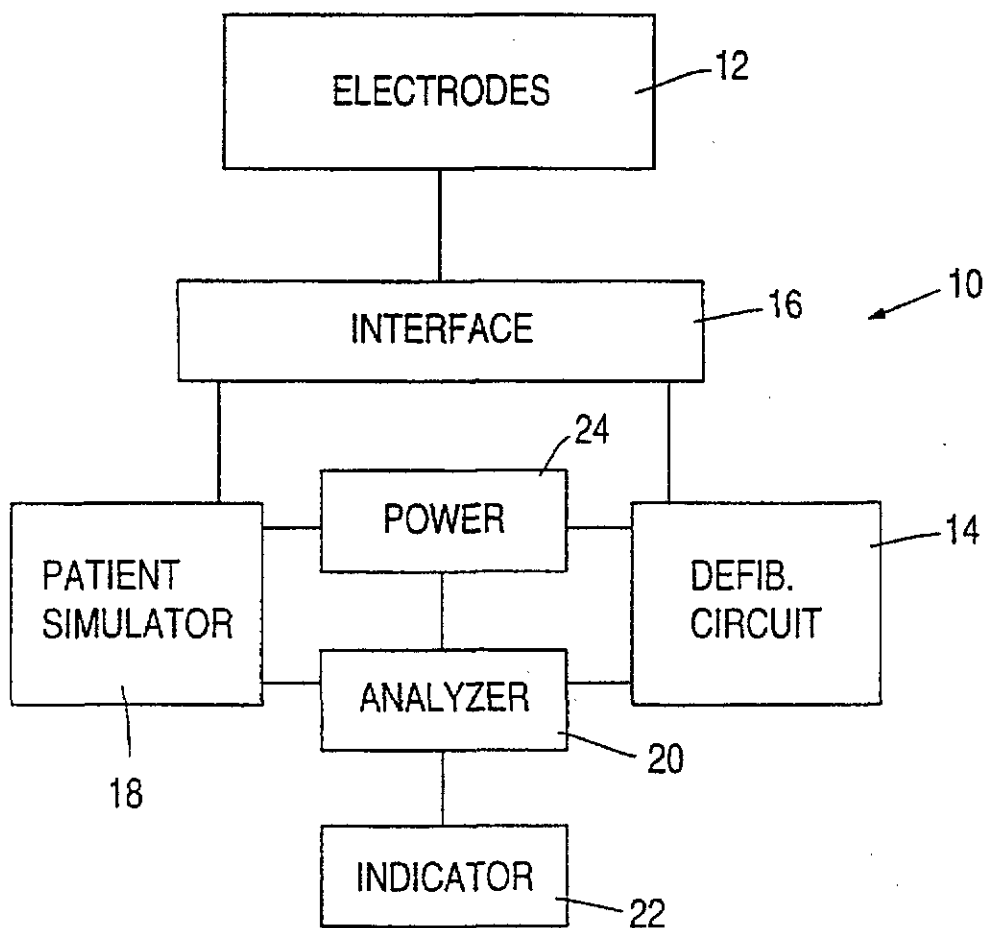


FIG. 1

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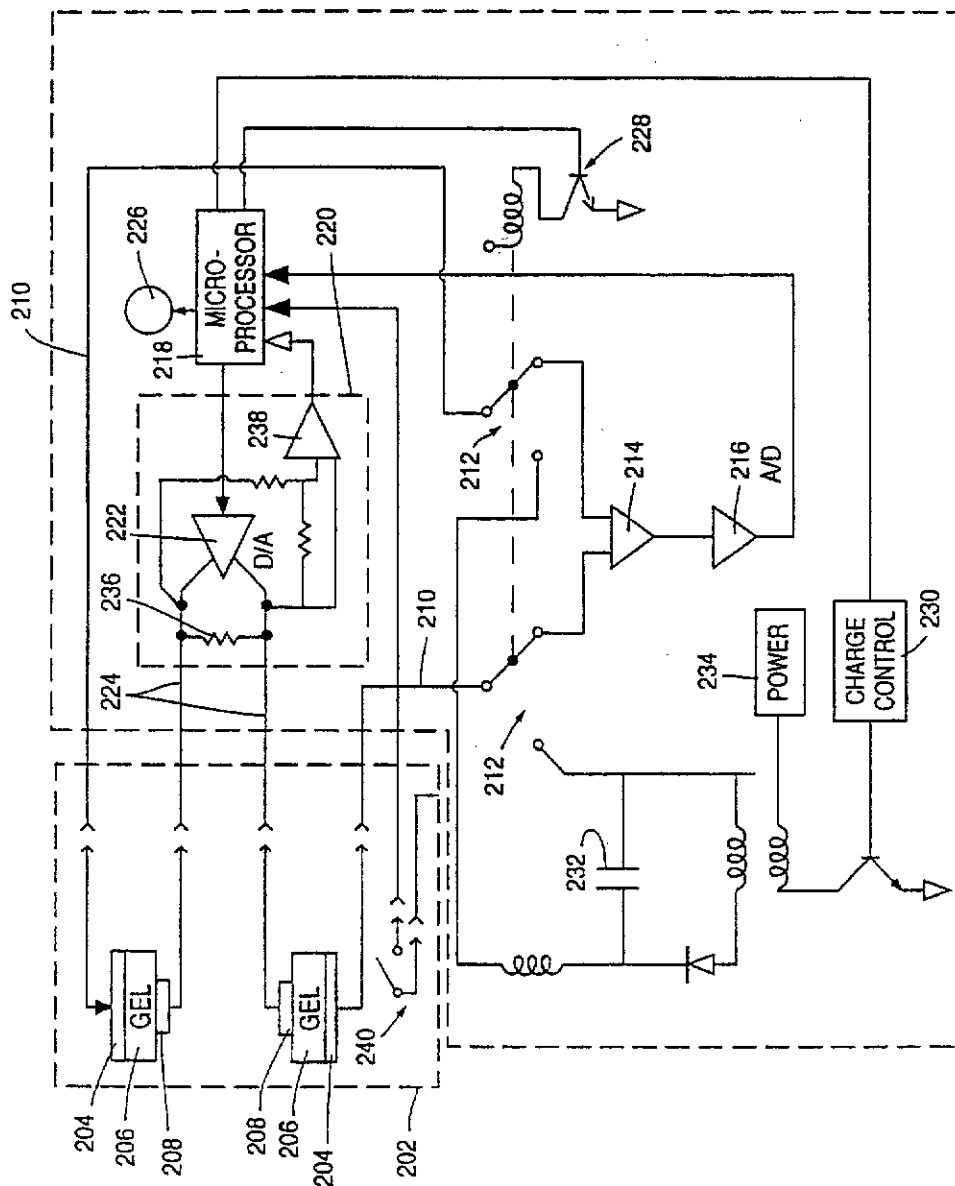


FIG. 2

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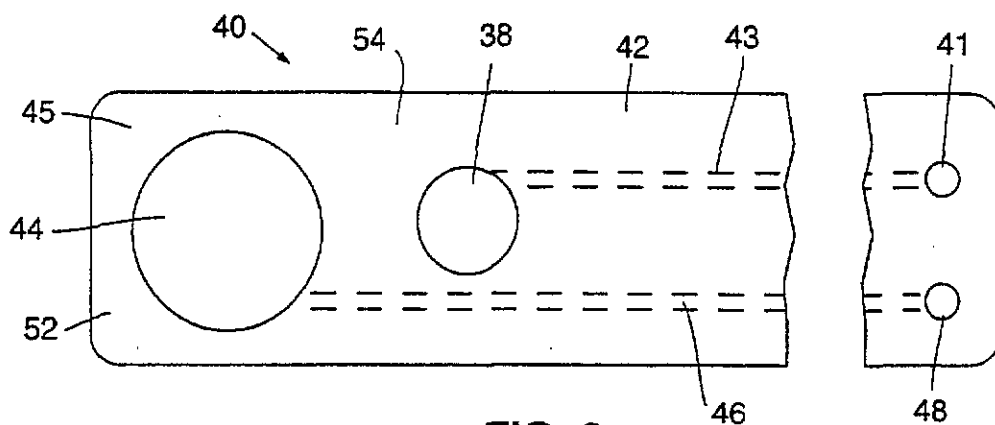


FIG. 3

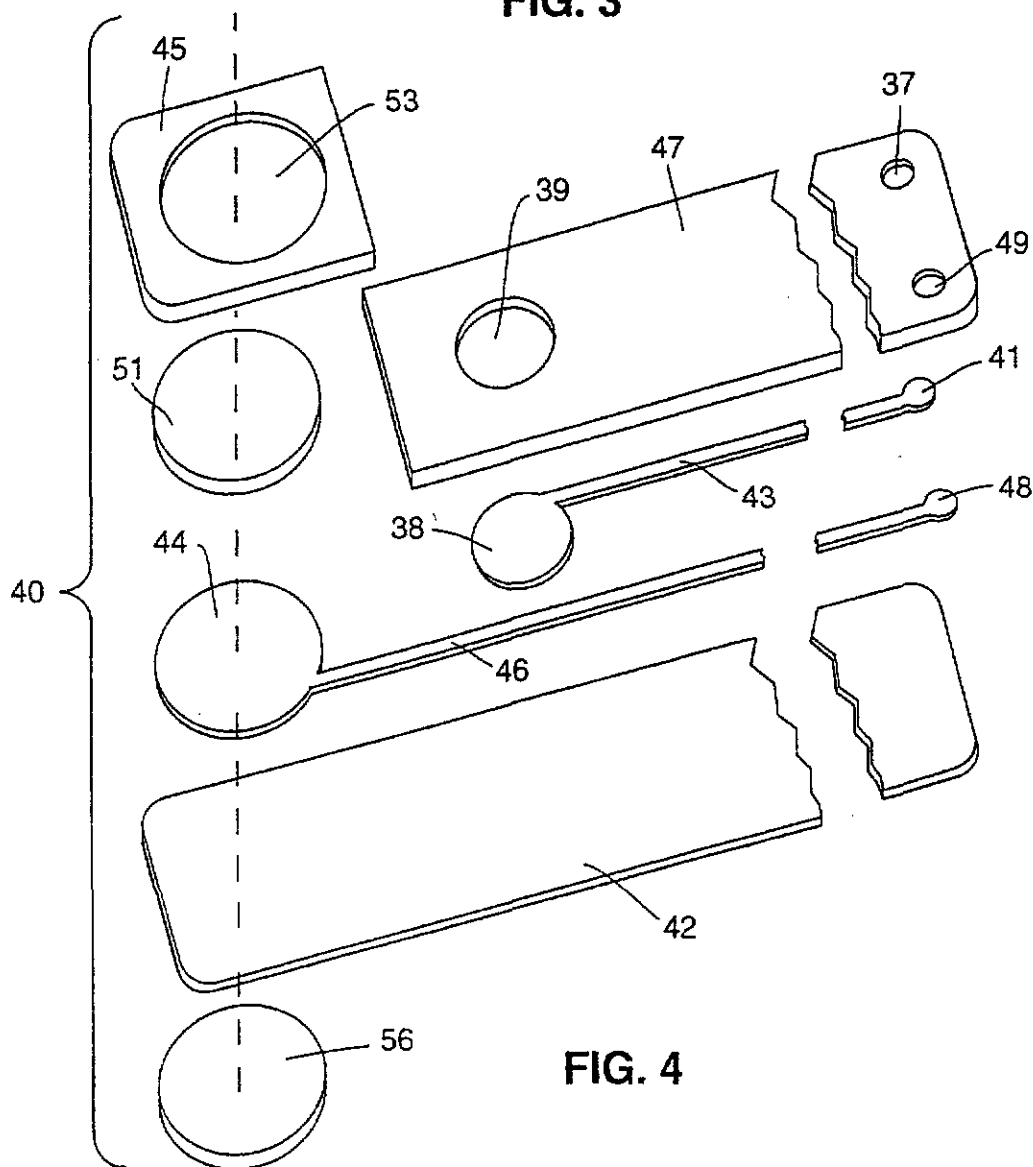


FIG. 4

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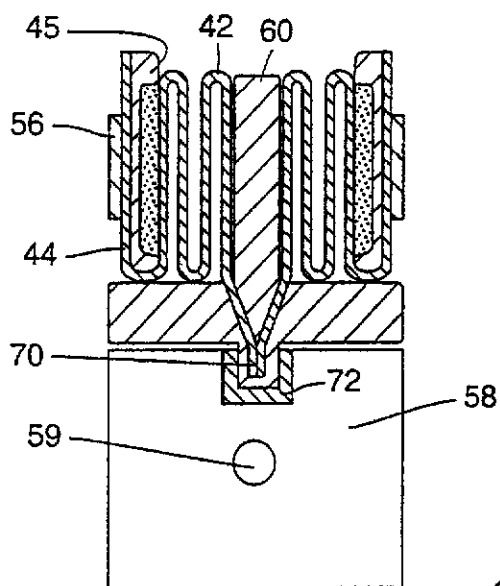


FIG. 5

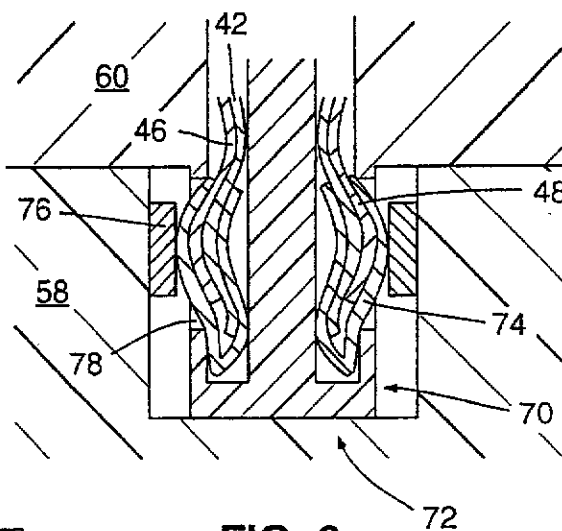


FIG. 6

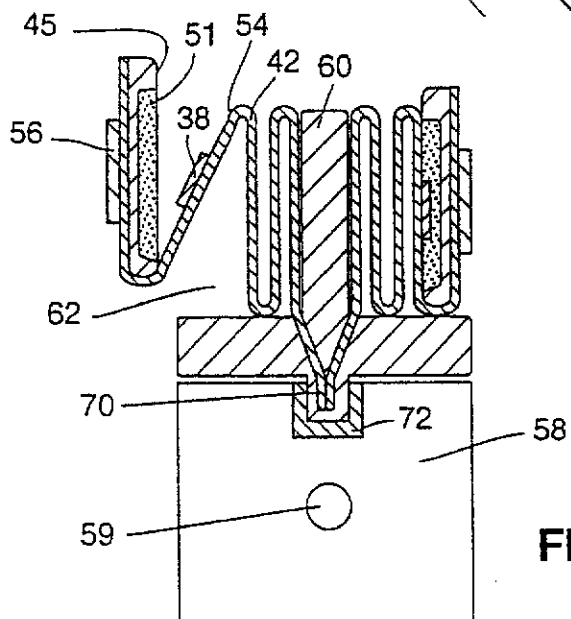


FIG. 7

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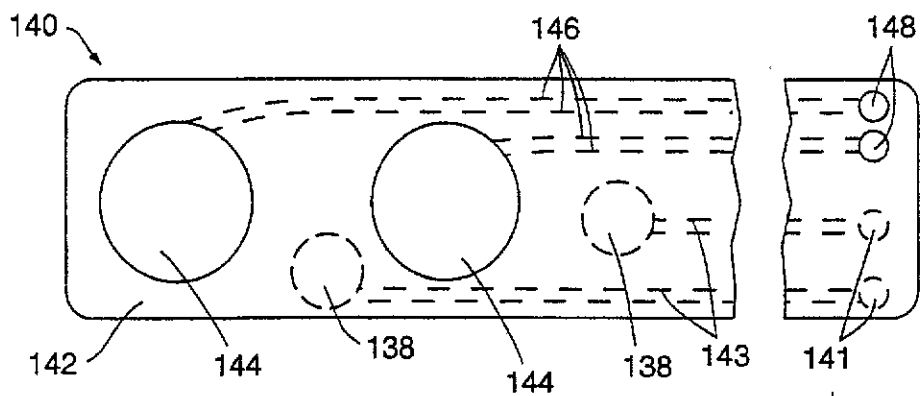


FIG. 8

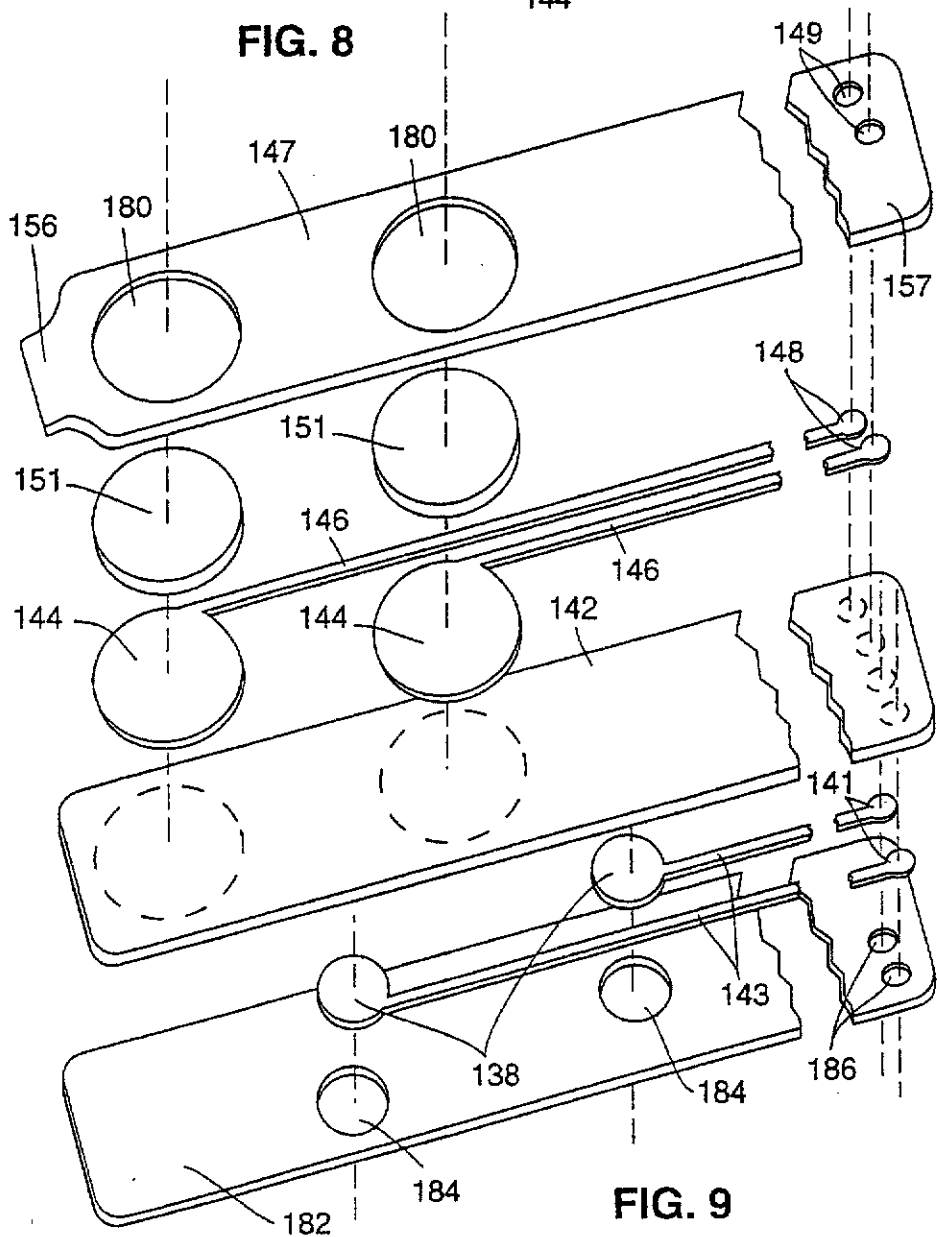


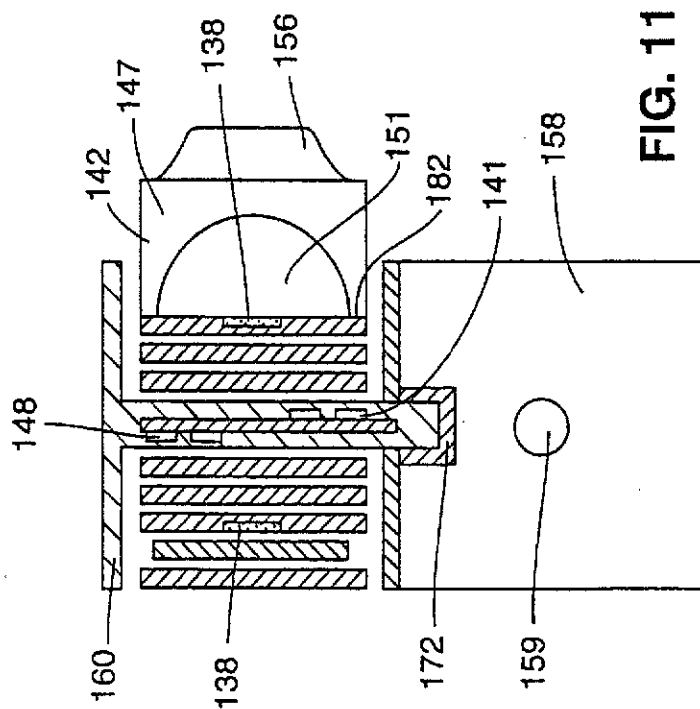
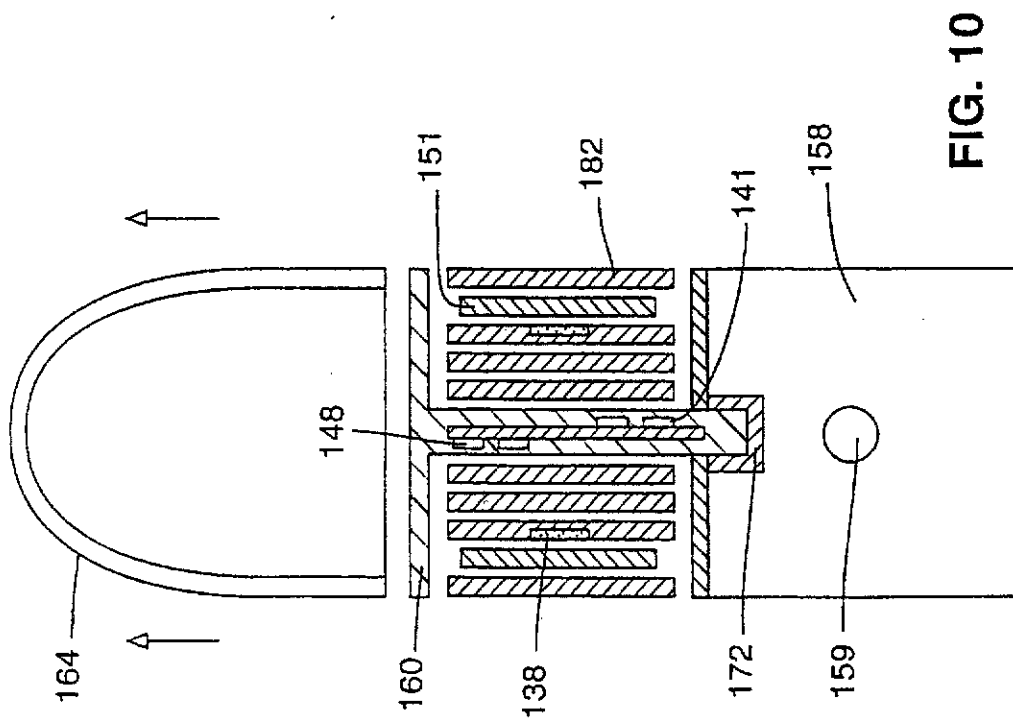
FIG. 9

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DEFIBRILLATOR SYSTEM CONDITION INDICATOR

This application is a continuation of application Ser. No. 08/063,631, filed May 18, 1993, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates generally to a method and apparatus for testing medical electrode systems and, in particular, to a method and apparatus for testing the operating condition of defibrillators and defibrillator electrodes and for providing the user with an indication of the system's condition.

Defibrillators apply voltage pulses to a patient's heart in response to a life-threatening condition such as cardiac arrest. External defibrillators deliver the voltage pulse through a pair of electrodes placed on the patient's chest or back by the attending medical personnel. The primary components of a defibrillator system are the defibrillator, which provides the voltage pulse, and the electrodes, which deliver the voltage pulse to the patient.

Prior art external defibrillator electrodes consist of a paddle having an electrode face electrically connected to the defibrillator by a cable. A conductive gel on the electrode face lowers the electrical resistance between the electrode and the patient. Disposable defibrillator electrodes are typically packaged with the gel pre-applied to the electrode face. Adhesive holds the electrodes in place on the patient. With standard reusable electrodes, on the other hand, the user must apply the gel before placing the electrodes on the patient. Handles on the back side of the electrode paddles enable the user to place the electrodes at the desired sites on the patient to hold the electrodes against the patient's skin.

SUMMARY OF THE INVENTION

One drawback of prior art defibrillator systems is the number of steps required to deploy the electrodes. Because defibrillators are used primarily in emergency situations, deployment and operation of defibrillator electrodes should be quick, easy and reliable. Prior art disposable defibrillator electrodes, however, require the following steps for deployment prior to delivery of the defibrillation pulse: connection of a cable to the defibrillator; inevitably, untangling of the cable; removal of the electrodes from their package; removal of the release liner covering the conductive gel over each electrode face and any adhesive surrounding the electrode; visual inspection of each electrode to determine whether it is usable; and application of the electrodes to the patient. Each of these steps takes time, and time is of the essence when trying to save a patient's life.

Furthermore, if a visual inspection or actual defibrillation attempt shows that either electrode is inoperative due to deterioration of the conductive gel, a broken conductor in the cable, a broken connection between the cable and the electrode, etc., then the deployment process must begin again, wasting even more time. What is needed, therefore, is a defibrillator system providing an indication of the condition of the defibrillator and defibrillator electrodes before deployment and placement on the patient.

Patient simulation units are available to test the operation of external defibrillators. Typically, the defibrillator output cable, i.e., the conductors leading to the electrodes, is connected to the simulation unit input. The defibrillator is then discharged as if the cable were attached to electrodes mounted on a patient. The simulation unit measures the defibrillator output pulse and gives an indication of the

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operating condition of the defibrillator. Because the defibrillator electrodes are not part of the test circuit, however, the simulation unit does not give any indication of electrode condition. Moreover, performing the test with patient simulation units adds to the burden of highly paid medical personnel, thereby raising the costs of the patient's care. What is needed, therefore, is a defibrillation system condition indicator that tests the electrodes and perhaps other parts of the defibrillator system automatically while the defibrillator is not in use.

This invention provides a defibrillator and electrode system that gives the user a visible and/or audible indication of the condition of the electrodes and other parts of the defibrillator system prior to deployment of the electrodes and use of the defibrillator. In a preferred embodiment of the method of this invention, a patient simulation and analyzer circuit within the defibrillator periodically tests the condition of the system and provides the user with a visual indication of the system's condition. One preferred embodiment of an electrode system useful for practicing this invention comprises a flexible substrate having a folded, undeployed position and an extended, deployed position. The substrate supports an electrode, an electrode tester conductive pad, and the electrical connections between the defibrillator and the electrode and between the conductive pad and the patient simulation and testing circuit. In its undeployed position, the electrode contacts the conductive pad to complete a circuit from the defibrillator, through the electrode to the patient simulation circuit.

In another preferred embodiment of an electrode system, the flexible substrate has a rolled or wound undeployed position and an unrolled or extended deployed position. The substrate supports a pair of electrodes, a pair of electrode tester conductive pads, and the electrical connections between these elements and the defibrillator and patient simulation circuits. In the substrate's undeployed position, the electrodes contact their respective conductive pads to complete a circuit from the defibrillator, through the electrodes to the patient simulation circuit.

The invention is explained in more detail below with reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a block diagram of a defibrillator system according to this invention.

FIG. 2 is a schematic circuit diagram of the defibrillator system of this invention.

FIG. 3 is an elevational view of an electrode system according to a preferred embodiment of this invention.

FIG. 4 is an exploded view of the electrode of FIG. 3.

FIG. 5 is a side cross-sectional view of a defibrillator electrode system according to a preferred embodiment, prior to deployment.

FIG. 6 is a cross-sectional view of a connector between an electrode system and an instrument.

FIG. 7 is a side cross-sectional view of the defibrillator electrode system of FIG. 5 with one electrode partially deployed.

FIG. 8 is an elevational view of an alternative embodiment of the electrode system of this invention.

FIG. 9 is an exploded view of the electrode system of FIG. 8.

FIG. 10 is a side cross-sectional view of the embodiment of FIG. 8, prior to deployment.

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FIG. 11 is a side cross-sectional view of the electrode system of FIG. 10 with the electrodes partially deployed.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 is a block diagram demonstrating the method and apparatus of this invention as applied to a defibrillator system. The defibrillator system 10 includes two or more electrodes 12 selectively connected to a standard defibrillator circuit 14 through an electrode interface 16. The defibrillator circuit applies a therapeutic voltage or current pulse to a patient through the electrodes under conditions controlled by logic within or associated with the circuit. The defibrillator may also receive information regarding the patient's heart activity from the electrodes in the form of ECG signals. The electrodes may be configured as described below or, alternatively, may be any defibrillator electrodes known in the art.

A patient simulator 18 is also selectively connected to the electrodes through interface 16. A defibrillator system analyzer 20 connected to the defibrillator circuit 14 and the patient simulator 18 controls the operation of the defibrillator circuit 14 during a test procedure, receives test information through the patient simulator 18, analyzes the test information, and indicates the test results via indicator 22. A power source 24 supplies power to the system.

The operation of the system of FIG. 1 is as follows. The system may be used to test the ability of the defibrillator circuit and electrodes to deliver a defibrillation pulse to a patient. Conductors leading from at least two electrodes are connected to the defibrillator circuit via an electrode interface. The electrode surfaces themselves, i.e., the portion of the electrodes that would be mounted on the patient during normal operation of the defibrillator, are electrically connected to the patient simulator, also via the electrode interface. A defibrillator test pulse is delivered from the defibrillator circuit to the electrodes, and the effect of the test pulse is measured at the patient simulator by the analyzer. The test pulse may be a voltage pulse of any magnitude, including but not limited to voltage magnitudes used for actual defibrillation. In that case, the analyzer will measure the current flowing through the patient simulator. The test pulse may also be a current pulse of any magnitude, in which case the analyzer will measure the voltage across the patient simulator. Other suitable tests will be apparent to those skilled in the art.

If the current or voltage measured at the patient simulator by the analyzer is below a predetermined threshold, the analyzer activates the indicator to show that the defibrillator is not operable. The indicator may be a visible indicator such as a light or a written message on a display, an audible sound, or any other suitable means of communicating an inoperable condition to the user.

The system may also be used to test the response of the logic portion of the defibrillator circuit to a signal originating with the patient. As in the other test, conductors leading from at least two electrodes are connected to the defibrillator circuit via an electrode interface. The electrode surfaces themselves, i.e., the portion of the electrodes that would be mounted on the patient during normal operation of the defibrillator, are electrically connected to the patient simulator, also via the electrode interface. A signal substantially similar to an ECG signal derived from a patient in ventricular fibrillation is generated by the patient simulator and delivered to the defibrillator circuit via the electrodes and

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electrode interface. In normal operation, the defibrillator should deliver a defibrillation pulse to the patient in response to such an ECG signal.

The analyzer monitors the output of the defibrillator circuit logic to the test ECG signal. If the defibrillator circuit logic fails to indicate that a defibrillation pulse is required, then the analyzer activates the indicator to show that the defibrillator is not operable. Again, the indicator may be a visible indicator such as a light or a written message on a display, an audible sound, or any other suitable means of communicating an inoperable condition to the user.

The ECG test may also be used to determine the response of the defibrillator circuit to a normal (non-fibrillating) ECG signal from a patient. As in the other tests, conductors leading from at least two electrodes are connected to the defibrillator circuit via an electrode interface. The electrode surfaces themselves, i.e., the portion of the electrodes that would be mounted on the patient during normal operation of the defibrillator, are electrically connected to the patient simulator via the electrode interface. A signal substantially similar to an ECG signal derived from a patient with a normal ECG, i.e., not in ventricular fibrillation, is generated by the patient simulator and delivered to the defibrillator circuit via the electrodes and electrode interface. In normal operation, the defibrillator should not deliver a defibrillation pulse to the patient in response to such an ECG signal.

The analyzer monitors the output of the defibrillator circuit logic to the test ECG signal. If the defibrillator circuit logic indicates that a defibrillation pulse is required, then the analyzer activates the indicator to show that the defibrillator is not operable. As with the other tests, the indicator may be a visible indicator such as a light or a written message on a display, an audible sound, or any other suitable means of communicating an inoperable condition to the user.

An indication that the defibrillator is not operable as a result of any of these tests could mean that there is a problem with the electrodes, the conductive gel on the electrodes, the electrode interface, and/or the defibrillator circuit itself. Therefore, if any test fails, the user may replace the electrodes and/or the electrode interface and run the test again. If the test indicates that the defibrillator system is now operable, then the problem was in the electrodes and/or electrode interface.

The analyzer can also be used to monitor the power level of the battery in a battery-operated defibrillator. If the battery level falls below a predetermined minimum, the analyzer activates the indicator to show that the defibrillator is not operable because of low battery level.

The frequency of any of these tests may be chosen to meet the system's requirements. For example, the power required for the defibrillator pulse tests may be so high that the frequency of this test must be limited in order to preserve battery life in battery-operated defibrillators. At the other extreme, the analyzer could monitor battery level continuously.

FIG. 2 is a circuit schematic showing one way of implementing the principal elements of the defibrillator system of the preferred embodiment. The portion of the schematic corresponding to the electrodes and electrode interface blocks of FIG. 1 is enclosed by a dotted line 202 and is referred to as the electrode apparatus or electrode system. The electrode apparatus 202 includes a pair of electrodes 204, conductive gel layers 206 covering the electrodes, and a pair of test pads or contacts 208 shown here to be in electrical contact with gel layers 206.

Electrodes 204 connect to a standard defibrillator circuit via conductors 210. In the circuit state shown here, the

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system is set to monitor patient ECG signals as if the electrodes were attached to a patient. In this monitoring state, switches 212 send the incoming signal from the electrodes through a preamp 214 and an A/D converter 216 for preprocessing before forwarding the signal to system microprocessor 218. Microprocessor monitors the received ECG signals and compares them to stored patterns or other criteria to distinguish normal patient ECG patterns from ECG patterns requiring action by the defibrillator system, as discussed below.

When configured as shown in FIG. 2, i.e., so that electrodes 204 are in electrical contact with test pads 208, the system is in test mode. The defibrillator system of this invention has a patient simulation and test circuit 220 to monitor the condition and integrity of the system prior to deployment of the electrodes and application of the electrodes to a patient. Periodically, microprocessor 218 sends a series of test signals to D/A converter 222, which converts the signals to their analog equivalent and transmits the signals to test pads 208 via conductors 224. Electrodes 204 retrieve the test signals as if the test signals were actual patient ECG signals and sends the signals back to the microprocessor through the ECG monitor circuit described above.

Preferably, the test signals are of at least two types: normal patient ECG waveforms, and ECG waveforms indicating a therapeutic pulse is required. The microprocessor analyzes the test signals as if they were actual patient ECG signals and decides whether or not to apply a therapeutic pulse to the electrodes. In ECG test mode, however, the actual pulse is not generated or applied. Rather, the microprocessor examines its own decision to determine if it was correct. If the outgoing ECG test signal from the microprocessor to the D/A converter was a normal ECG waveform and the microprocessor determines from the incoming test ECG signal that a therapeutic pulse is required, the system is faulty, and the microprocessor indicates the fault on a fault indicator 226. Likewise, if the outgoing ECG test signal from the microprocessor to the D/A converter was an ECG waveform indicating the need for a therapeutic pulse and the microprocessor determines from the incoming test ECG signal that a therapeutic pulse is not required, the system is faulty, and the microprocessor indicates the fault on a fault indicator 226. If, on the other hand, the microprocessor determines correctly the required course of action, the fault indicator is not activated.

If the system passes the ECG tests, it then performs a defibrillator test by generating a pulse through its normal pulse generating circuitry and sending the pulse to the electrodes 204. To initiate the pulse test, the microprocessor sends a charge command to a charge controller 230, which begins charging capacitor 232 in a known manner from power supply 234. When the charge on capacitor 232 has reached the required level (either the charge level required for normal operation or some other test charge level), switch relay 228 moves switches 212 to their other position. This switch position permits the pulse circuit to discharge the capacitor to deliver a damped sinusoidal shock to the electrodes.

The pulse transmitted by the electrodes through conductive gel layers 206 to test pads 208 is monitored by the test circuit 220 across a patient load simulator 236. The signal is reduced by a divider circuit and sent to microprocessor 218 via A/D converter 238. If the pulse received by the microprocessor does not meet predetermined criteria (such as voltage levels and signal waveform shape), the microprocessor indicates a system fault by activating fault indicator

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226. So long as the system passes the tests, the tests are repeated periodically until the electrodes and their gel layers are removed from test pads 208 as determined by a deployment detector 240.

FIGS. 3 and 4 show an electrode apparatus according to a preferred embodiment of this invention. As shown in FIGS. 3 and 4, the electrode apparatus 40 has a relatively stiff electrode body 45 attached to a flexible substrate 42 with a medical grade adhesive. In this embodiment, substrate 42 is a polymer such as polyester or Kapton, approximately 3 mils thick. The length of substrate 42 depends on the requirements of the application. Electrode body 45 is preferably made from a light-weight, closed-cell foam approximately 25 mils thick.

An electrode disk 44 is disposed within electrode body 45. Electrode disk 44 is preferably a circular piece of metal foil, such as 3 mil tin, approximately 80 cm² in area, attached to substrate 42 with a suitable medical grade adhesive. Electrode disk 44 is covered with a layer of conductive gel 51 in a known manner. The thickness of gel layer 51 is 25 mils to make its top surface approximately even with the surrounding electrode body surface. Medical grade adhesive is disposed in adhesive area 52 on the top surface of electrode body 45 surrounding the opening 53 for electrode disk 44.

A first conductor 46 and a first electrical attachment pad 48 are formed on, or attached to, flexible substrate 42. Conductor 46 and electrical attachment pad 48 are preferably 3 mil tin foil formed integrally with electrode disk 44 and attached to substrate 42 with adhesive. A second conductor 43, a second electrical attachment pad 41 and a test pad 38 are formed on, or attached to, substrate 42. Conductor 43, attachment pad 41 and test pad 38 are also preferably formed as an integral piece of metal foil attached to substrate 42 with adhesive.

An insulating cover 47 is adhesively attached over substrate 42 and conductors 43 and 46. Cover 47 has a silicon release coating on its top side. Openings 49 and 37 are formed in cover 47 so that attachment pads 48 and 41, respectively, can make electrical contact with a connector, as described below. An additional opening 39 is formed in cover 47 so that test pad can make electrical contact with electrode 44 through gel 51, also as described below.

In FIGS. 5-7, a pair of the electrodes shown in FIGS. 3 and 4 are mounted in a retainer for use with a defibrillator system. FIG. 5 shows the electrodes in a predeployment storage position. In this position, the flexible substrate 42 of each electrode is folded in an accordion fashion and placed in retainer 60.

The portion of substrate 42 on which the attachment pads 41 and 48 are located extends into a retainer connector area 70 for electrical attachment to a corresponding connector 72 on the defibrillator 58. FIG. 6 shows the details of one embodiment of the connectors for attachment pads 48 on the two electrode apparatuses. The same arrangement may be used for attachment pads 41.

Metal crimps 74 at the end of substrate 42 make electrical contact with attachment pads 41 and 48. The crimps 74 partially extend through openings 78 in the connector portion 70 of retainer 60. When the retainer connector portion is inserted into the connector portion of the defibrillator 58, crimps 74 make electrical contact with defibrillator contacts 76. The resilient action of the crimps 74 also provide the mechanical attachment of retainer 60 to defibrillator 58. The contacts 76 for each electrode and for each test pad are connected to the defibrillator electronics in a known manner.

The test pads 38, their associated conductors 43, their attachment pads 41, and the retainer connector 70 serve as

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the interface between the electrodes and a patient simulator circuit within defibrillator 58 during the defibrillator system tests described above. An indicator 59 such as a light or an audible annunciator is provided to inform the user of test results.

Likewise, the conductors 46 and attachment pads 48 on the substrates are the interface between the electrodes and the defibrillator for delivery of the defibrillating voltage pulse and/or for monitoring of the electrical activity of the patient's heart during normal operation of the defibrillator. The positions of the electrode apparatus during the two operational modes will be explained with reference to FIGS. 5 and 7.

In the folded position shown in FIG. 5, the conductive gel 51 covering the electrode disk 44 of each electrode apparatus lies in electrical contact with its respective test pad 38. This contact closes the circuit going from one electrode through the patient simulation circuit to the other electrode so that the patient simulation tests can be performed.

Also, in the folded position shown in FIG. 5, the adhesive surrounding the electrode disk lies against an area 54 on the top surface of substrate 42. The top surface of substrate 42 is coated with a suitable release coating such as silicon in at least release area 54. The release coating enables the adhesive to peel away from substrate 42 during deployment of the electrode, as discussed below. The covering action of the substrate over the conductive gel also helps keep the conductive gel from drying out during storage. A handle 56 attached to the back side of electrode body 45 lies in position in which it can be grasped by a user during deployment of the electrodes.

FIG. 7 demonstrates deployment of the electrodes. As shown in FIG. 7, the user pulls electrode body 45 out of retainer 60 by grasping handle 56. As it moves out of the retainer, the electrode disk 44 and its conductive gel layer 51 peel away from substrate surface 42. Movement of the conductive gel layers 51 of the electrodes away from their respective test pads 38 breaks the circuit through the patient simulator. After removal from the retainer, the electrodes may be placed on a patient and used for monitoring the patient's heart activity and for applying therapeutic electrical pulses in the usual manner.

FIGS. 8-11 show an alternative embodiment of this invention. As shown in FIGS. 8 and 9, the electrode apparatus 140 has a flexible body or substrate 2, preferably formed from $\frac{1}{16}$ " closed cell foam. A backing layer 182 is attached to the underside of substrate 142 with a medical grade adhesive. Backing layer 182 may be formed from Tyvek or any other suitable material.

The underside of backing layer 182 is coated with a silicon release material. A pair of test pads 138 are adhesively attached to the top of backing layer 182 over a pair of openings 184 whose diameters are slightly smaller than the diameters of test pads 138. Openings 184 provide access to test pads 138 from the underside of backing layer 182.

Conductors 143 lead from test pads 138 to attachment pads 141. Openings 186 beneath attachment pads 141 have diameters slightly smaller than the diameters of attachment pads 141. Each set of test pad, conductor and attachment pad is preferably formed from a single piece of tin metal foil 3 mils thick.

A pair of electrodes 144 are adhesively attached to the top of substrate 142. Conductors 146 lead from electrodes 144 to attachment pads 148. Each set of electrode, conductor and attachment pad is preferably formed from a single piece of tin metal foil 3 mils thick. The surface area of each electrode

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is preferably 80 cm². A layer of conductive gel 151 covers each electrode. The thickness of the conductive gel layer is preferably 25 mils.

An insulating cover 147 is attached to the top side of substrate 142 with medical grade adhesive. Cover has openings 180 for the electrodes and openings 149 for the attachment pads. Openings 180 have diameters slightly smaller than the diameters of their respective electrodes, and openings 149 have diameters slightly smaller than their respective attachment pads. Medical grade adhesive covers all of the top surface of cover 147 except for handle area 156 and connector area 157 for attachment of the electrode apparatus to a patient.

FIGS. 10 and 11 show the electrode apparatus of this embodiment mounted in a retainer. As seen in FIG. 10, prior to deployment, the electrode apparatus is wound around a spool-shaped retainer 160 mounted on top of a defibrillator 158. The portion of the electrode apparatus on which the attachment pads 141 and 148 are located extend into the center of the retainer spool where they make electrical connection with conductors (not shown) that connect to the defibrillator connector 172. The metal crimps shown in FIG. 6 may be used for this purpose. A protective cover 164 may be kept over retainer spool 160 until the electrodes are to be deployed.

In the undeployed state shown in FIG. 10, the conductive gel layers 151 and the adhesive coating on cover layer 147 face the inward toward the center of the retainer spool, and the release coating on the underside of backing layer 182 faces outward from the center. Thus, when the electrode apparatus is wound about itself, the conductive gel layers 151 and the adhesive coating on the cover layer lie against the silicon release coating of the backing layer 182. Also, the conductive gel layers 151 of each electrode lie in electrical contact against their respective test pads 138, as shown. This contact closes the circuit going from one electrode through the patient simulation circuit to the other electrode so that the patient simulation tests can be performed. An indicator 159 such as a light or an audible annunciator is provided to inform the user of test results.

To deploy the electrode apparatus of this embodiment, the protective cover 164 is removed, and the electrode apparatus is unwound from retainer spool 160 by pulling on handle or tab 156, as shown in FIG. 11. The release coating on backing layer 182 permits the conductive gel layers 151 and the adhesive on cover layer 147 to peel away. Movement of the conductive gel layers 151 of the electrodes away from their respective test pads 138 breaks the circuit through the patient simulator. The electrode apparatus is then applied to the patient and used for monitoring the patient's heart activity and for applying therapeutic electrical pulses in the usual manner.

The electrode apparatus and spool retainer remain attached to the defibrillator during use. The conductors 146 and attachment pads 148 provide the electrical connection between the electrodes 144 and the defibrillator for delivery of the defibrillating voltage pulse and/or for monitoring of the electrical activity of the patient's heart. After use, the retainer spool and the electrode apparatus it houses can be discarded and replaced with a new electrode set.

Modifications may be made to the described embodiments without departing from the scope of the invention. For example, other electrode configurations may be used with the test apparatus of this invention so long as an appropriate electrode interface is provided. When selecting electrode materials, it should be remembered that repeated tests could

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cause corrosion of the electrodes and/or test pads if the tests are not charge-balanced. In addition, while in the preferred embodiment the defibrillator runs the electrode integrity tests, it should be understood that a separate test unit may be used instead. The electrodes would then have to be disconnected from the test unit and connected to a defibrillator before actual use. Also, while this invention has been described in the context of defibrillators and defibrillator electrodes, it should be understood that the invention applies to medical electrodes used with other instruments, such as ECG monitors.

Other modifications will be apparent to those skilled in the art.

What is claimed is:

1. A defibrillator system comprising:
 - a defibrillator, the defibrillator comprising a defibrillator circuit and an electrode interface, the defibrillator circuit comprising an energy source, the electrode interface comprising conductors in electrical communication with the energy source;
 - means for periodically operating the energy source to discharge a test pulse through the conductors;
 - a patient simulator communicating with the conductors;
 - a test pulse analyzer communicating with the conductors and the patient simulator; and
 - a fault indicator communicating with the test pulse analyzer.
2. The defibrillator system of claim 1 further comprising electrodes attached to the conductors.
3. The defibrillator system of claim 1 wherein the means for periodically operating comprises a microprocessor.
4. The defibrillator system of claim 1 wherein test pulse analyzer comprises a microprocessor.
5. The defibrillator system of claim 4 wherein the test pulse analyzer further comprises means for sensing an electrical parameter.
6. The defibrillator system of claim 1 wherein the fault indicator comprises a visual display.
7. The defibrillator system of claim 6 wherein the visual display comprises a light.
8. A defibrillator system comprising:
 - a defibrillator, the defibrillator comprising a defibrillator circuit and an electrode interface, the defibrillator circuit comprising an energy source, the electrode interface comprising conductors in electrical communication with the energy source;
 - means for periodically delivering a test signal through the conductors;
 - a patient simulator communicating with the conductors;
 - a test signal analyzer communicating with the conductors and the patient simulator; and
 - a fault indicator communicating with the test signal analyzer.
9. The defibrillator system of claim 8 further comprising electrodes attached to the conductors.
10. The defibrillator system of claim 8 wherein the means for periodically delivering a test signal comprises means for operating the energy source to discharge a test pulse through the conductors.
11. The defibrillator system of claim 8 wherein the means for periodically delivering a test signal comprises a microprocessor.
12. The defibrillator system of claim 11 wherein the means for periodically delivering a test signal further comprises a D/A converter.

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13. The defibrillator system of claim 8 wherein the test signal analyzer comprises a microprocessor.

14. The defibrillator system of claim 13 wherein the test signal analyzer further comprises an A/D converter.

15. A defibrillator system comprising:

defibrillator, the defibrillator comprising a defibrillator circuit and an electrode interface, the defibrillator circuit comprising an energy source, the electrode interface comprising conductors in electrical communication with the energy source;

means for periodically delivering a test signal through the conductors;

a patient simulator communicating with the conductors;

a test signal analyzer communicating with the conductors and the patient simulator; and

a fault indicator communicating with the test signal analyzer,

wherein the test signal is an ECG signal pattern.

16. A defibrillator system comprising:

a defibrillator, the defibrillator comprising a defibrillator circuit and an electrode interface, the defibrillator circuit comprising an energy source, the electrode interface comprising conductors in electrical communication with the energy source;

means for periodically delivering a test ECG signal through the conductors;

means for periodically delivering a test pulse through the conductors;

a patient simulator communicating with the conductors;

an analyzer communicating with the conductors and the patient simulator; and

a fault indicator communicating with the analyzer.

17. A test system for a defibrillator, the system comprising:

an energy source;

conductors in electrical communication with the energy source;

means for periodically operating the energy source to discharge a test pulse through the conductors;

a patient simulator communicating with the conductors;

a test pulse analyzer communicating with the conductors and the patient simulator; and

a fault indicator communicating with the test pulse analyzer.

18. The system of claim 17 further comprising electrodes attached to the conductors.

19. The system of claim 17 wherein the means for periodically operating comprises a microprocessor.

20. The system of claim 17 wherein test pulse analyzer comprises a microprocessor.

21. The system of claim 20 wherein the test pulse analyzer further comprises means for sensing an electrical parameter.

22. The system of claim 17 wherein the fault indicator comprises a visual display.

23. The system of claim 22 wherein the visual display comprises a light.

24. A test system for a defibrillator, the system comprising:

an energy source;

conductors in electrical communication with the energy source;

means for periodically delivering a test signal through the conductors;

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a patient simulator communicating with the conductors;
 a test signal analyzer communicating with the conductors
 and the patient simulator; and
 a fault indicator communicating with the test signal
 analyzer.

25. The system of claim 24 further comprising electrodes
 attached to the conductors.

26. The system of claim 24 wherein the means for
 periodically delivering a test signal comprises means for
 operating the energy source to discharge a test pulse through
 the conductors.

27. The system of claim 24 wherein the test signal is an
 ECG signal pattern.

28. The system of claim 24 wherein the means for
 periodically delivering a test signal comprises a micropro-
 cessor.

29. The system of claim 28 wherein the means for
 periodically delivering a test signal further comprises a D/A
 convertor.

30. The system of claim 24 wherein the test signal
 analyzer comprises a microprocessor.

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31. The system of claim 30 wherein the test signal
 analyzer further comprises an A/D convertor.

32. A test system for a defibrillator, the system compris-
 ing:

an energy source;

conductors in electrical communication with the energy
 source;

means for periodically delivering a test ECG signal
 through the conductors;

means for periodically delivering a test pulse through the
 conductors;

a patient simulator communicating with the conductors;

an analyzer communicating with the conductors and the
 patient simulator; and

a fault indicator communicating with the analyzer.

* * * * *

Exhibit G





US006230054B1

(12) **United States Patent**
Powers

(10) **Patent No.:** US 6,230,054 B1
(45) **Date of Patent:** May 8, 2001

(54) **APPARATUS FOR CONTROLLING
DELIVERY OF DEFIBRILLATION ENERGY**

6,104,953 * 8/2000 Leyde 607/4
6,119,039 * 9/2000 Leyde 607/5

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(73) **Assignee:** Agilent Technologies, Inc., Palo Alto, CA (US)

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(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

Primary Examiner—Jeffrey R. Jastrzab

(21) **Appl. No.:** 09/299,180

(57) **ABSTRACT**

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(51) **Int. Cl.⁷** A61N 1/39

(52) **U.S. Cl.** 607/5

(58) **Field of Search** 607/4.5, 63

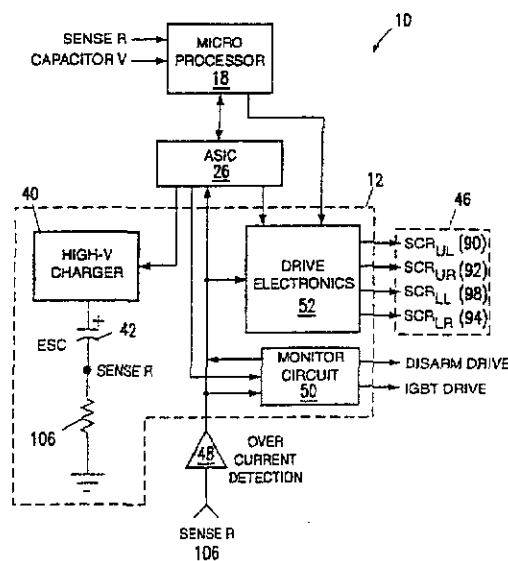
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An automatic external defibrillator is described that includes a high voltage delivery circuit for producing an electrical pulse to defibrillate a patient. In a preferred embodiment the electrical pulse is a biphasic or multiphasic electrical pulse. In one embodiment, the delivery circuit includes a high voltage capacitor coupled with a bridge circuit. The capacitor stores electrical energy for delivery to the patient, and the bridge circuit has four switching elements that are selectively switched to steer the current through the patient. A disarm circuit shunts the bridge circuit and operates to route energy away from the bridge circuit in the event a fault condition is detected, such as a short circuit at the patient electrodes. An example disarm circuit is a series-connected SCR and resistor. Also, a limiting circuit element (such as a resistor or an inductor) is provided in series with the capacitor. Together with the disarm circuit, the limiting circuit element reduces the voltage experienced by the bridge circuit switching elements when switched off in response to the detected fault condition. Consequently simpler, more robust, and less expensive high voltage delivery circuits are provided, as compared to conventional defibrillator circuit designs. A snubber circuit is also provided to prevent voltage from reaching the patient when the device is in standby mode.

58 Claims, 3 Drawing Sheets



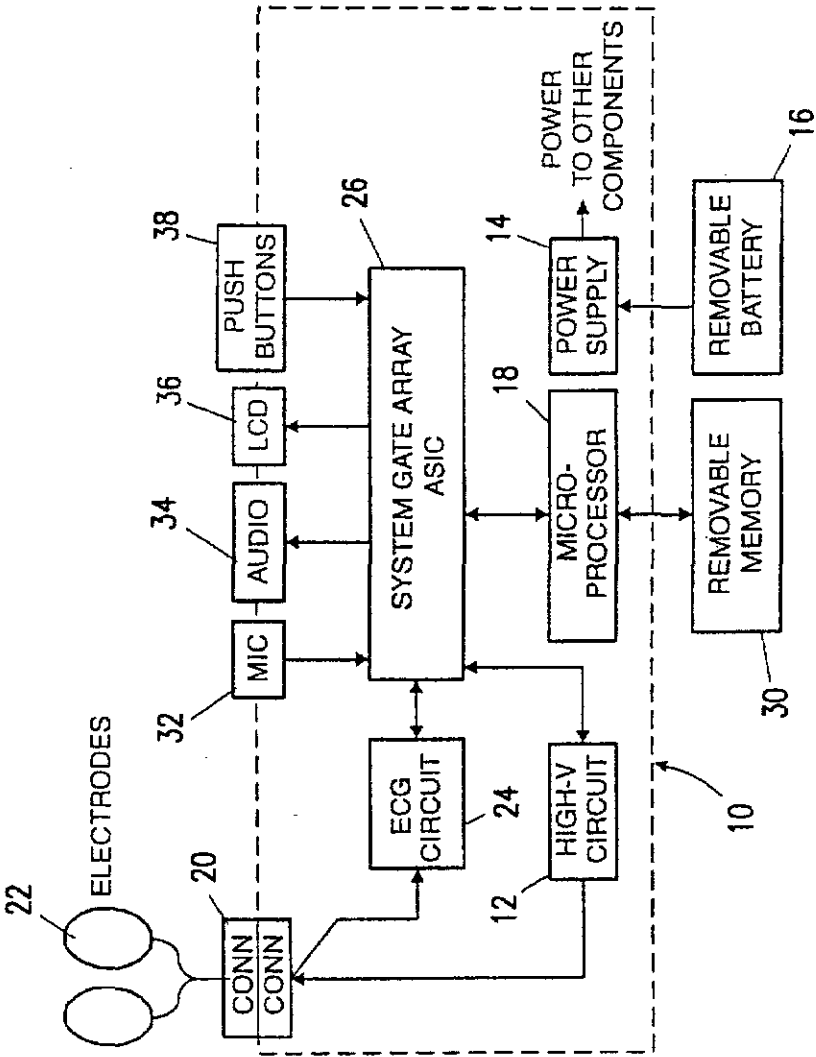


FIG. 1

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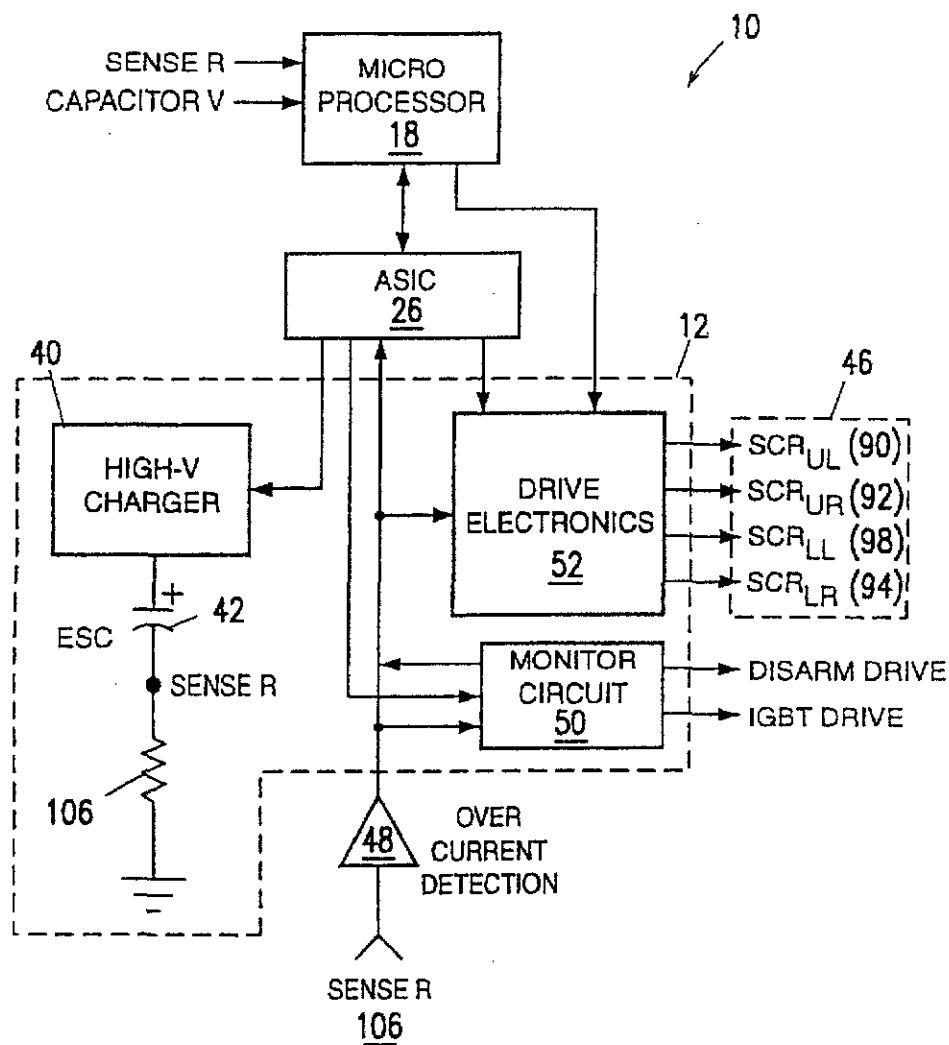


FIG.2

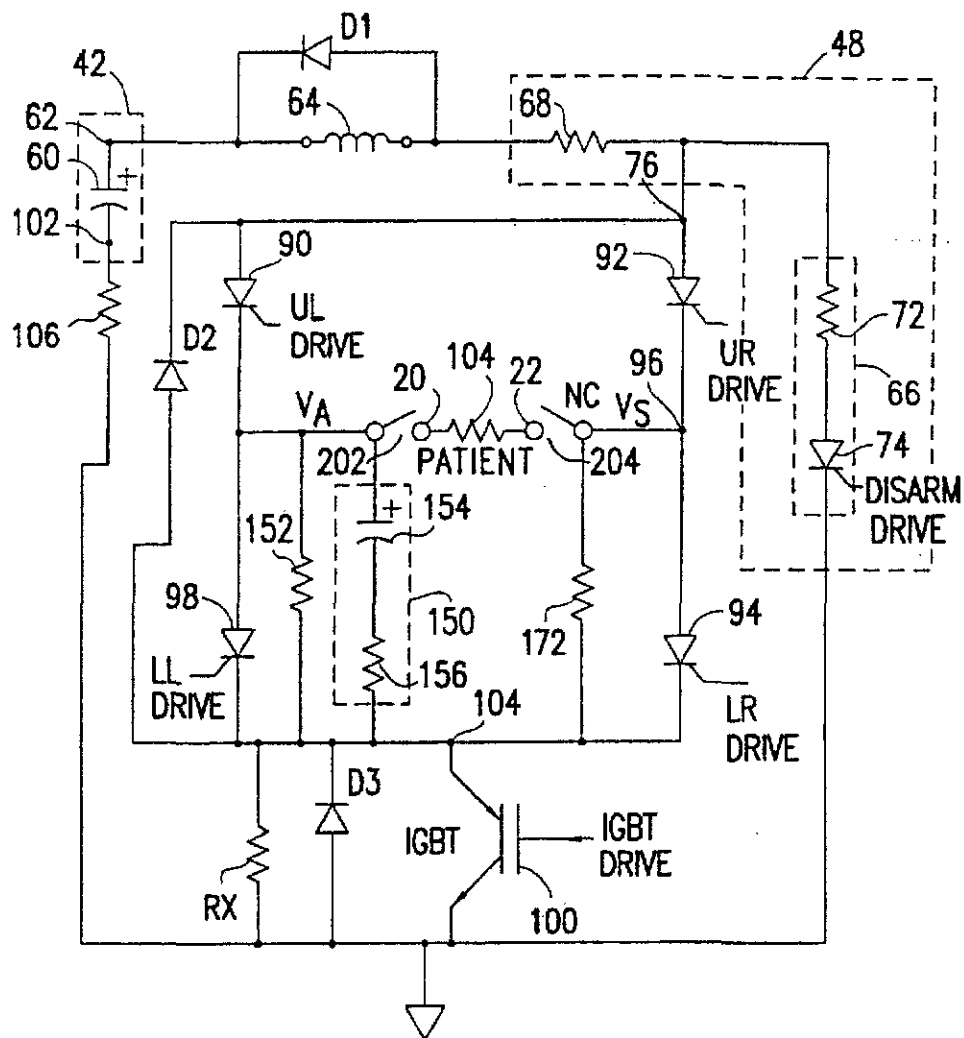


FIG.3

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APPARATUS FOR CONTROLLING DELIVERY OF DEFIBRILLATION ENERGY

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to a method and apparatus for delivering electrical energy produced by a defibrillator to a patient experiencing ventricular fibrillation ("VF"), and more particularly to a method and apparatus for controlling the delivery of electrical energy produced by an external defibrillator. The circuit of this invention allows for active and passive protection of the high energy delivery circuit in the event of a fault condition. The circuit also enables the patient to be protected from high voltage when the device is in standby or monitoring mode. The circuit provides a reliable and safe means of protecting the H-bridge from an over-current condition while increasing patient and operator safety. The circuit also has the advantage of being simple and inexpensive while maintaining a high degree of effectiveness.

2. Description of the Prior Art

Each day thousands of Americans are victims of cardiac emergencies. Cardiac emergencies typically strike without warning, oftentimes striking people with no history of heart disease. The most common cardiac emergency is sudden cardiac arrest ("SCA"). It is estimated that more than 1000 people per day are victims of SCA in the United States alone; this translates into one death every two minutes.

SCA occurs when the heart stops pumping blood. Usually SCA is due to abnormal electrical activity in the heart, resulting in an abnormal rhythm (arrhythmia). One such abnormal rhythm, VF, is caused by abnormal and very chaotic electrical activity in the heart. During VF the heart cannot pump blood effectively. VF may be treated by applying an electric shock to the patient's heart through the use of a defibrillator. The shock clears the heart of the abnormal electrical activity (in a process called "defibrillation") by depolarizing a critical mass of myocardial cells to allow spontaneous organized depolarization to resume, thus restoring normal function. Because blood may no longer be pumping effectively during VF, the chances of surviving decrease with time after the onset of the emergency. Brain damage can occur after the brain is deprived of oxygen for four to six minutes.

External defibrillators send electrical pulses to the patient's heart through electrodes applied to the patient's torso. External defibrillators are typically located and used in hospital emergency rooms, operating rooms, and emergency medical vehicles. Of the wide variety of external defibrillators currently available, automatic and semi-automatic external defibrillators (AEDs) are becoming increasingly popular because they can be used by relatively inexperienced personnel. Such defibrillators can also be especially lightweight, compact, and portable.

AEDs must include circuitry capable of handling the high voltages and high currents associated with electrical defibrillation. In some instances, suitable components with the required electrical characteristics are not readily available, and the AED designer must instead rely on multiple component configurations where, functionally, a single component would suffice.

Additionally, AEDs require monitoring and control circuitry to protect the patient, as well as the AED circuitry itself, in the event of a fault condition. One common fault condition occurs as a result of variations in load impedances,

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such as those resulting from short circuits or open circuit conditions. The high voltages applied to patients may also create situations, such as arcing between electrodes or arcing between patient wires, that could also lead to failure of the therapy electronics if not properly protected. Such monitor and control circuitry is made increasingly complex by the multiple component configurations included in currently available AEDs.

One method employed by currently available defibrillators to solve this problem is by measuring patient impedance using a low-level signal prior to delivering a shock. The disadvantage of this method is that it relies heavily on the accuracy of the low-level signal measurement relative to the actual impedance (i.e., impedance detected during the high voltage pulse delivered during defibrillation). As will be appreciated by those of skill in the art, the low-level signal cannot predict all behaviors of the external circuit during defibrillation. An example of a condition that cannot be predicted is arcing.

Another method, employed by the ForeRunner® (manufactured by Heartstream, Inc., Seattle, Wash.), is to measure impedance during the initial portion of the waveform and to allow the circuit to continue if impedance is within tolerable limits. Toward that end a 20 Ω resistor is placed in series for the first 100 μ s that the voltage is delivered. During that time, the resistance across the electrodes is tested to ensure that the connection has not been shorted by monitoring the voltage across a 0.05 Ω current sense resistor. Providing a resistance in series during the initial voltage delivery, ensures that the circuit will not be subjected to excessive current in the event that there is a short condition. However, if a fault occurs after the first 100 μ s the circuit could be exposed to excessive currents.

What is needed, therefore, is an AED with a fault protection circuit that is capable of actively protecting the high voltage H-bridge. Protection of the H bridge can be accomplished by switching the bridge off during a fault condition, and/or passively protecting the high voltage bridge, e.g. by allowing the circuit to tolerate the fault condition. Further what is needed is a way to protect the H-bridge from valid load conditions while minimizing the exposure of the patient, or patient simulated load, to the energy stored in the AED. Finally what is needed is a way to protect the operator and/or patient in the event of a discharge to an abnormally high patient load.

SUMMARY OF THE INVENTION

In accordance with the present invention, an apparatus and method is provided for producing and controlling a high energy pulse for application to a patient experiencing VF. A storage circuit stores electrical energy and a steering circuit delivers the electrical energy from the storage circuit to the patient. A protection circuit is coupled with the storage circuit and with the steering circuit. The protection circuit selectively controls the delivery of the electrical energy from the storage circuit to the steering circuit. The protection circuit may include a disarm circuit that selectively shunts the electrical energy away from the steering circuit and patient. The protection circuit may include a limit circuit that limits the rate of delivery of the electrical energy from the storage circuit to the steering circuit. The rate at which electrical energy is delivered is measured and compared to a predetermined range of acceptable rates. If the rate falls within the acceptable range, then electrical energy continues to be delivered. If, however, the rate does not fall within the accepted range, the disarm circuit is enabled and the delivery

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of the electrical energy to the steering circuit is interrupted. Determination of whether the rate falls within a predetermined acceptable range occurs all the time, thus the disarm circuit can be enabled at any time the rate falls outside the accepted range. The limit circuit and disarm circuit together may limit a maximum voltage applied across the steering circuit when the delivery of electrical energy is interrupted.

This invention provides the advantage of limiting the exposure of the external circuit to high voltage/energy in the event of an over-current load condition. These advantages are achieved with the use of lower cost, readily available components.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a functional block diagram depicting a defibrillator according to an embodiment of the present invention.

FIG. 2 is a functional block diagram depicting a high-voltage delivery circuit included in the defibrillator of FIG. 1.

FIG. 3 is a schematic diagram depicting certain details of a first embodiment of the high-voltage delivery circuit of FIG. 2.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Currently available external defibrillators provide either a monophasic or biphasic electrical pulse to a patient through electrodes applied to the chest. Monophasic defibrillators deliver an electrical pulse of current in one direction. Biphasic defibrillators deliver an electrical pulse of current first in one direction and then in the opposite direction. When delivered external to the patient, these electrical pulses are high energy (typically in the range of 30 J to 360 J). This invention may be employed by defibrillators that generate monophasic, biphasic or multiphasic waveforms. Additionally, this invention may be employed by defibrillators that allow the user to select the waveform type.

Defibrillators employing a monophasic waveform are well known in the art. While this invention may be used with a defibrillator employing a monophasic waveform, it is believed that the solution described herein is primarily beneficial for defibrillators that deliver biphasic or multiphasic waveforms.

An example of an AED employing a biphasic waveform is described in U.S. Pat. No. 5,607,454, entitled "Electrotherapy Method and Apparatus," the disclosure of which is incorporated herein by reference. Such defibrillators employ a high voltage bridge circuit for steering the biphasic pulse applied to the patient. The energy delivered to the patient is first stored in an energy storage circuit such as a capacitor, with associated voltages commonly in the range of 1000-2500 V. Prior to delivery of the electrical energy to the patient, one or more of the components of the bridge circuit must withstand this voltage without significant leakage.

Should energy delivery via the bridge circuit be halted due to a fault condition, the corresponding currents and voltages handled by the bridge components are quite high. Given the components currently available to the AED designer, today's bridge circuits commonly include as many as eight to ten distinct switching elements. Correspondingly, the control circuitry associated with switching these elements is relatively complex. The circuit component numbers and complexity required by such AEDs can result in increased expense, potentially lowered reliability, and reduced portability.

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In accordance with the present invention, embodiments of an external defibrillator are provided that have a high voltage bridge circuit using only five switching elements to steer the biphasic or multiphasic pulse. In an electrical path separate from the bridge circuit, a sixth switching element is provided for discharging/discharging the energy storage capacitor in the event of a fault. An additional switching element or elements can be provided for current initiation and commutation control. In the following description, certain specific details are set forth in order to provide a thorough understanding of embodiments of the present invention. It will be clear, however, to one skilled in the art, that the present invention can be practiced without these details. In other instances, well-known circuits have not been shown in detail in order to avoid unnecessarily obscuring the description of the various embodiments of the invention. Also not presented in any great detail are those well-known control signals and signal timing protocols associated with the internal operation of defibrillators.

FIG. 1 is a functional block diagram depicting a defibrillator or AED 10 having a high-voltage delivery circuit 12 in accordance with an embodiment of the present invention. The AED 10 includes a power supply 14, which is powered by an energy source such as a removable battery 16 and provides power to other components of the AED. A micro-controller or processor 18 controls the operation of the various components of the AED 10. The high-voltage delivery circuit 12 delivers a pulse of electrical energy to a patient via an electrode connector or interface 20 and electrodes 22.

An electrocardiogram (ECG) circuit 24 acquires and processes the patient's ECG signals through the electrodes 22 and sends the signals to the processor 18 via a system gate array 26. The system gate array 26 is preferably a custom application-specific integrated circuit (ASIC) integrating many of the defibrillator functions (including user interface control and many of the internal functions) and interfacing the processor 18 with other components of the AED 10. Providing the separate system gate array or ASIC 26 allows the processor 18 to focus on other tasks. Of course, the functionality of the ASIC 26 could be included within the operations performed by the processor 18, or could be replaced by discrete logic circuit components or a separately dedicated processor.

The AED 10 also includes a memory device 30. As depicted in FIG. 1, memory device 30 is a removable PCMCIA card or magnetic tape. AED 10 also includes user interface components such as a microphone 32, an audio speaker 34, an LCD display panel 36, and a set of push-button controls 38. Those skilled in the art will understand that a number of other components are included within the AED 10 (e.g., a system monitor and associated status indicators), but are not shown in order to avoid unnecessarily obscuring the description of embodiments of the invention.

As shown in FIG. 2, the high-voltage delivery circuit 12 includes a number of functional circuit blocks which are both monitored and controlled by the ASIC 26. A high-voltage charging circuit 40, such as a flyback power supply, responds to one or more control signals issued by the ASIC 26 and generates electrical energy for provision to a capacitor 42. By controlling the high voltage charger 40, the ASIC can correct an over voltage condition as a result of measuring voltage on the capacitor 60 while it is charging.

The capacitor 42, which could be an energy storage circuit ("ESC"), stores the electrical energy for delivery to the patient. The electrical energy is delivered to an energy

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transfer or steering circuit 46 (comprising four silicon controlled rectifier switches, SCR_{UL} , SCR_{UR} , SCR_{LL} , and SCR_{LR}) through drive electronics 52. The steering circuit 46 in turn delivers the electrical energy to the patient via the connector 20 and electrodes 22 (shown in FIG. 1).

The protection circuit 48 (shown in FIG. 3) functions to limit energy delivery from the ESC 42 to the steering circuit 46 (and hence to the patient) and to discharge or otherwise disarm the ESC 42 in the event of a fault condition. A monitor circuit 50 senses operations of both the protection circuit 48 and the steering circuit 46 and reports the results of such monitoring to the ASIC 26. ASIC 26 provides instructions to the monitor circuit 50 which controls the disarm drive and IGBT drive of the circuit shown in FIG. 3 to prevent an over-current condition on the bridge. The above-described operations of the steering circuit 46 and the protection circuit 48 are controlled by a drive circuit 52 issuing a plurality of drive signals. Operation of the drive circuit 52 is, in turn, controlled by one or more control signals provided by the ASIC 26 and the microprocessor 18.

FIG. 3 is a more detailed depiction of the invention shown in FIG. 2.

An ESC 42 is provided which is a capacitor (or multiple capacitor unit) 60. Suitable capacitance is approximately 100 μF ; the ESC 42 is capable of regularly and reliably storing energy up to approximately 220 J (which corresponds to a voltage of approximately 2100 VDC). The capacitor 60 has a positive terminal or node 62. The energy storage circuit provides energy to a steering circuit 46 which, in turn, controls the delivery of energy to a patient 104. The steering circuit 46 enables the circuit to deliver either a biphasic or multiphasic energy pulse to the patient 104.

The steering circuit 46 is configured as an "H-bridge", with four switching elements. The steering circuit 46 includes an upper-left (UL) switching element, such as SCR_{UL} 90, and an upper-right (UR) switching element, such as SCR_{UR} 92. The anode of each of the SCRs 90, 92 is connected to an upper node 76, and the cathode of each of the SCRs is connected to a respective one of two patient terminals 96 (which, in turn, are coupled with the connector 20 and respective ones of the electrodes 22 of FIG. 1). The control terminal or gate of each of the SCRs 90, 92 receives a respective UL or UR drive signal produced by the drive circuit 52 (shown in FIG. 2) to selectively switch the SCRs on. A patient 104 is represented by a resistor, shown in the electrical location of the patient during defibrillator operations.

The steering circuit 46 also includes a lower-left (LL) switching element, such as SCR_{LL} 98, and a lower-right (LR) switching element, such as SCR_{LR} 94. The anode of the SCR_{LL} 98 and the anode of the SCR_{LR} 94 are each connected to a respective one of the patient terminals 96. The cathode of the SCR_{LL} 98 and the cathode of SCR_{LR} 94 are each connected to a lower terminal or node 104 of the steering circuit 46. The control terminal or gate of the SCR_{LL} 98 receives an LL drive signal from the drive circuit 52 (shown in FIG. 2) to selectively switch the respective SCR on. The control terminal or gate of SCR_{LR} 94 receives a LR drive signal from the drive circuit 52 to selectively switch the SCR on and off.

A high-voltage diode D_2 is connected in parallel to SCR_{UL} 90 and SCR_{LL} 98 at nodes 76 and 104. Diode D_2 operates to snub inductance in the patient load when the bridge is turning off the current, for example during the commutation interval.

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A sense resistor 106 is connected in series with the steering circuit 46, between lower terminal 104 of the steering circuit 46 and the negative terminal of the energy steering circuit 42 at node 102. A suitable resistance value for the sense resistor 106 is approximately 50 m Ω , and is preferably of the low-value precision resistor type commonly used as an electric shunt in ammeters. In a preferred embodiment, the monitor circuitry 50 (shown in FIG. 2) is an over-current/waveform abort control logic (OIWAL). If an over-current detection is "TRUE," or the switch disarm signal is asserted, the OIWAL performs the necessary steps to shut down the patient load current and safely disarm the ESC 42. Further details of how the drive is disarmed is discussed below.

Additionally, the information from the sense resistor 106 can be provided to the microprocessor 18. The microprocessor can then perform time-integration calculations to obtain information concerning the voltage across the capacitor 60 during defibrillation energy delivery operations.

A limit circuit includes an inductor 64 is connected in series between the positive terminal of the energy storage circuit 42 at node 62 and resistor 68. A suitable value for the inductor 64 is between 100 and 200 μH , preferably 150 μH . A high voltage diode D_1 is connected in parallel to the inductor 64 at nodes 62 and 80. The inductor 64 controls the rate at which the current that is delivered to the steering circuit 46 by the ESC 42 can increase. The advantage of providing the inductor 64 in series with the ESC 42 is that by slowing the rate at which the current through the steering circuit 46 can ramp up, additional time is provided for the monitor circuit 50 to instruct a disarm circuit to disconnect the bridge in the event of an over-current situation. Further, the inductor 64 controls dI/dt such that a fixed current threshold can be used for over-current detection. The advantage of providing diode D_1 in parallel to the inductor 64 is that the diode functions to snub the inductor during current interruption.

The protection circuit 48 of FIG. 2 is shown in FIG. 3 as two distinct subcircuits—namely, a current limit resistor 68 and a disarm circuit 66.

The current limit resistor 68 is connected in series between inductor 64 (which is connected to the positive terminal 62 of the capacitor 60) and the upper node 76 of the steering circuit 46. The limit resistor 68 limits maximum current flow from the inductor 64 through the steering circuit; a suitable resistance value for the limit resistor 68 is between approximately 3–7 Ω , more preferably 5 Ω .

The disarm circuit 66 includes a disarm resistor 72 (with a suitable resistance value being between approximately 3–7 Ω , more preferably 5 Ω) and an SCR 74. The disarm resistor 72 and SCR 74 are connected in series between the upper terminal 76 of the steering circuit 46 and the negative terminal 102 of the capacitor 60, thereby providing an electrical path shunting the steering circuit. If a fault condition is detected (such as an over-current condition), the disarm SCR 74 is switched on and the energy stored in the capacitor 60 substantially dissipated in the disarm resistor 72 and the limit resistor 68. The disarm SCR 74 is selectively switched on by a disarm drive signal provided by the drive circuitry 52 shown in FIG. 2.

Another aspect of the invention is that it provides a mechanism to isolate the patient from the high voltages when the defibrillator is in monitoring mode, thus keeping current from leaking onto the patient 104 prior to delivery of the therapeutic energy pulse. Resistors 152 and 172 function to ground the patient and the ECG circuitry 24, thus pre-

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venting current leakage during standby operations. Resistors 152 and 172 are selected to drain the upper SCR leakage currents when the ESC 42 is charging or charged in normal operation. IGBT 100 is left on (during the monitoring mode) to facilitate bleed off of the leakage through resistors 152 and 172. The impedance of resistors 152 and 172 is selected so that under worst case operating conditions a minimal voltage is present at the isolation relay 200 contacts. A suitable value for resistors 152 and 172 is between approximately 5–10 Ω , more preferably 9.4 k Ω .

An important aspect of this invention is that leakage resistors 152 and 172 are returned to the collector of IGBT 100. This allows the resistors 152, 172 to have a low resistance value without compromising commutation of the H-bridge. For example, if the resistors were returned to ground, the current flowing through the upper SCRs might exceed the hold current and the SCRs would stay on between phases. If the SCRs stayed on, a cross-conduction of the H-bridge would occur. These resistors also serve as a path to remove charge from a snubber network 150 during the commutation interval.

Additionally resistor R_x and high voltage diode D_3 are provided in parallel to IGBT 100 collector-emitter at nodes 104 and 82. Diode D_3 prevents a negative voltage across IGBT 100 during high impedance aborts. A high impedance abort occurs, for example, when the patient impedance at 104 is greater than 200 Ω . Typically when patient impedance exceeds 200 Ω the shock is aborted because it is not possible to complete the therapeutic shock without resulting in an over-voltage condition on the IGBT 100 during the commutation interval.

Resistor R_x bleeds off IGBT collector-emitter capacitance during commutation interval. This results in a reduction or elimination of residual voltage at V_A or V_S prior to initiation of the next phase of the shock. Where V_A is the voltage at the apex of the patient; V_S is the voltage at the sternum of the patient.

The snubber network 150 has a capacitor 154 and a resistor 156. The capacitor 154 and resistor 156 are connected in series. Capacitor 154, resistor 156 and inductor 64 function to limit the rate of change of voltage across the SCR_{LL} 98 when patient impedance is high. By controlling the rate of change of voltage (dV/dT), SCR_{LL} 98 will not accidentally turn on when current is flowing from SCR_{UL} 90 to SCR_{LR} 94 during the first phase of the energy delivery, which might otherwise occur as a result of the voltage change at node 148. Suitable values for capacitor 154 is from 0.007 to 0.03 μ F, preferably 0.01 μ F; suitable values for resistor 156 is from 25 to 100 Ω , preferably 50 Ω .

Isolation relay 200, comprising switches 202 and 204, is provided respectively between nodes 20 and 22 and patient 104. The isolation relay 200 is used to prevent leakage, impedances or voltages from interfering with the ECG acquisition function during monitoring and charging activities.

Like resistor 152, resistor 172 is provided on the other side of the H-bridge to isolate the patient 104 and the ECG circuitry 24, thus preventing current leakage during standby operations.

The above-described control signals may be provided by any of a wide variety of suitable drive circuits known to those skilled in the art. For example, the control signals applied to the gates of the bridge SCR_{UL} 90, SCR_{UR} 92, SCR_{LR} 94, SCR_{LL} 98, may each be suitably provided by a corresponding pulse transformer. The secondary coil of each of the transformers may be tied directly to the corresponding

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SCR gate, with the SCRs designed so that, once triggered and conducting, they will tolerate the short-circuit on the gate-cathode junction that occurs with transformer saturation. Because of the more precise timing requirements for defibrillator disarm operations, the disarm SCR 74 may, for example, be suitably controlled by a logic-level MOSFET switching a bipolar pull-up transistor (not shown). A switching circuit is also provided, shown as IGBT 100. The control signal applied to turn IGBT 100 on and off may, for example, be provided by bipolar pull-up and pull-down transistors (not shown), respectively, which may themselves be triggered by logic-level MOSFET devices (not shown).

The operation of the circuit structure shown in FIG. 3 will now be described. The capacitor 60 is charged by the charging circuitry 40 (shown in FIG. 2) to approximately 2000–2400 V, with the positive terminal 64 having a positive voltage relative to the negative terminal 102. During monitoring operations, the capacitor 60 is fully charged, but no defibrillation energy is delivered to the patient pending completion of ECG monitoring by the ECG circuit 24 (shown in FIG. 1). During standby operation IGBT 100 is on. If the results of the ECG monitoring indicate that defibrillation energy should be delivered to the patient the isolation relay 200 is closed. After an appropriate settling time, SCR_{UL} 90 and SCR_{LR} 94 are turned on and conduction is initiated. During the first phase of the biphasic pulse delivery, current flows from the positive terminal 62 of the capacitor 60 through the inductor 64, limit resistor 68, SCR_{UL} 90, the patient, SCR_{LR} 94, IGBT 100 and the sense resistor 106. When the microprocessor 18 has determined that phase 1 of the waveform is nearing completion, it signals the ASIC 26 to terminate phase 1. Following a brief pause of approximately 400 μ s, known as the commutation interval (or interphase delay), IGBT 100 is turned on and the approximately 10 μ s later SCR_{UR} 92 and SCR_{LL} 98 are turned on, and electrical energy is further discharged through the patient in the second phase of the biphasic pulse applied to the patient. As will be appreciated by those of skill in the art, delivery of a multiphasic pulse would require these steps to be repeated until the desired number of phases had been achieved. Thus, no specific description of how to deliver a multiphasic pulse is provided.

SCRs of the type suitable for use in the steering circuit 46 and as the disarm SCR 74 are currently readily available. These SCRs can withstand the high voltage and currents occurring during defibrillation operations, and can also survive relatively intense transient effects, such as might occur due to a short circuit or when energy delivery operations are interrupted.

As is well known in the art, one disadvantage of SCRs is that, once turned on, they are not easily turned off absent a forced current commutation. Thus, the energy steering circuit 46 requires at least one switching element that can be turned off for purposes of current commutation and reversing polarity during biphasic energy delivery. Switching elements that can withstand the high voltages and currents that may occur during defibrillation operations are not readily or cost-effectively available. For example, readily available IGBTs can safely withstand a voltage of 1200 V applied across the collector and emitter. In the past IGBTs have been stacked in an effort to overcome limitations on voltage tolerances. However, this solution involves unnecessary complications to the bridge design. Those skilled in the art will appreciate that, if the above-described IGBT 100 were itself to "open" the steering circuit 46 to interrupt delivery of electrical energy from the capacitor 60 (when fully or near-fully charged), the voltage experienced by the

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IGBT 100 would significantly exceed the rated 1200 V limit thereby damaging the circuit.

In accordance with the embodiment of the invention depicted in FIG. 3, the IGBT 100 is protected from elevated voltages and currents. In the event of an over-current condition (caused, for example, by a short-circuit at the patient electrodes 22), the disarm SCR 74 is first switched on to begin discharging the capacitor 60 through the limit resistor 68 and the disarm resistor 72. Because the resistors 68 and 72 form a voltage divider, the IGBT 100 can then be shut off at a lower collector-to-emitter voltage than would otherwise be the case. Thus, a single IGBT 100 may be employed, rather than the conventional multiple component approach found in current AED designs. Further, because the disarm circuit is external to the H-bridge, the ESC 42 can be safely disarmed without exposing the patient 104 to high voltages. In the event of a high impedance load fault, the microprocessor 18 can signal the OIWAL to protect the H-bridge and the patient load in a similar fashion. As will be appreciated by those of skill in the art a high impedance load fault can occur at several times during operation of the bridge. Initially, a high impedance load fault can occur during the initial voltage delivery (for example where the electrode pads are shorted out). Additionally, a high impedance load fault can occur at the end of phase one, where, for example, more than 1200 V remains on the capacitor. In either situation, the microprocessor signals the OIWAL to protect the patient and the H-bridge by aborting the shock. However, where the load fault is detected at the end of a phase, the result is that the shock delivered comprises only the phases delivered. Specifically, where the fault occurs at the end of phase one, the result is that a monophasic shock to the patient.

The embodiment of the present invention shown in FIG. 3 provides a relatively inexpensive and robust defibrillation energy delivery circuit. In contrast with currently available designs, the provision of the disarm circuit 66 allows a bridge circuit design comprised of four individual switching elements, which are readily available and low cost SCRs. In the event of a fault condition, such as an over-voltage condition, the energy stored in the capacitor 60 can be similarly discharged safely through the disarm circuit 48.

In operation, the disarm circuit 66 is triggered in response to an over-current condition. Approximately 1 μ s later, the IGBT 100 is turned off by OIWAL. In a preferred embodiment, the over-current trip point is set at approximately 80 Amps. At the maximum voltage of the capacitor the di/dt of the inductor is approximately 14 A/ μ s. When the SCR is fired the resistors form a dividing network (with a ratio of approximately 2:1), where the top of the H-bridge is at the center point. When the IGBT 100 is turned off, the maximum voltage at the collector is $V_{CAP}/2$. More importantly, as the IGBT 100 is turning off there is effectively a 5 Ω snubber resistance across the collector-emitter junction. This provides a high degree of margin for RBSOA, which is the safe operating area of the IGBT 100 during turn-off.

Those skilled in the art will understand that certain of the circuits and components shown in FIGS. 1-3 have not been described in particular detail. In such case, the circuits and components are the type whose function and interconnection is well known in the art, and one skilled in the art would be able to use such circuits and components in the described combination to practice the present invention. The internal details of these particular circuits are not critical to the invention, and a detailed description of such internal circuit operation is therefore not required.

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It will be appreciated that, while specific embodiments of the invention have been described herein for purposes of illustration, various modifications may be made without deviating from the spirit and scope of the invention. Those skilled in the art will appreciate that many of the advantages associated with the circuits described above in connection with FIG. 3 may be provided by other circuit configurations. Those skilled in the art will also understand that a number of suitable circuit components, other than those particular ones described above, can be adapted and combined in a variety of circuit topologies to implement a high voltage delivery circuit in accordance with the present invention. Accordingly, the invention is not limited by the disclosed embodiments, but instead the scope of the invention is determined by the following claims.

What is claimed:

1. A circuit for producing a high energy pulse for application to a patient experiencing ventricular fibrillation, comprising:

- a storage circuit operable to store electrical energy;
- a steering circuit coupled with the storage circuit, the steering circuit being adapted for coupling with the patient and operable to deliver the electrical energy from the storage circuit to the patient; and
- a protection circuit coupled with the storage circuit and with the steering circuit and operable to respond to a detected fault condition to selectively control the delivery of electrical energy from the storage circuit to the steering circuit.

2. A circuit according to claim 1 wherein the protection circuit includes a disarm circuit operable to selectively shunt delivery of the electrical energy away from the steering circuit.

3. A circuit according to claim 2 wherein the disarm circuit includes a switching element and a resistive element, the switching element selectively electrically connecting the storage circuit with the resistive element to dissipate the electrical energy therein.

4. A circuit according to claim 3 wherein the switching element is a silicon-controlled rectifier.

5. A circuit according to claim 1 wherein the protection circuit includes a limit circuit coupled between the storage circuit and the steering circuit and operable to limit the rate of current increase from the storage circuit to the steering circuit.

6. A circuit according to claim 5 wherein the limit circuit includes a resistive element operable to limit current flow from the storage circuit to the steering circuit.

7. A circuit according to claim 1 wherein the protection circuit includes a limit circuit coupled between the storage circuit and the steering circuit and operable to limit the time rate of change of delivery of the electrical energy from the storage circuit to the steering circuit.

8. A circuit according to claim 7 wherein the limit circuit includes an inductive element coupling the storage circuit with the steering circuit, the inductive element operable to limit the time rate of change of current flow from the storage circuit to the steering circuit.

9. A circuit according to claim 1 wherein the protection circuit includes a disarm circuit and a protection circuit, the disarm circuit being operable to selectively shunt delivery of the electrical energy away from the steering circuit, and the limit circuit being operable to limit delivery of the electrical energy from the storage circuit to the steering circuit, the disarm circuit and limit circuit together operable to substantially limit a maximum voltage applied across the steering circuit.

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10. A circuit according to claim 1 wherein the storage circuit includes a capacitor having first and second terminals and operable to store the electrical energy therebetween, wherein the steering circuit includes a bridge circuit coupled with the first and second terminals of the capacitor and operable to deliver a biphasic pulse of the electrical energy to the patient, wherein the protection circuit includes a series-connected switching element and a first resistive element shunting the bridge circuit, and wherein the protection circuit includes a second resistive element coupling the first terminal of the capacitor with the bridge circuit, the switching element operable to electrically connect the first and second terminals together through the first and second resistive elements to substantially dissipate the electrical energy therein, the first and second resistive elements forming a voltage divider to limit a maximum voltage applied across the bridge circuit.

11. A circuit according to claim 1 wherein the storage circuit includes a capacitor having first and second terminals and operable to store the electrical energy therebetween, wherein the steering circuit includes a bridge circuit coupled with the first and second terminals of the capacitor and operable to deliver a biphasic pulse of the electrical energy to the patient, wherein the protection circuit includes a series-connected switching element and a resistive element shunting the bridge circuit, and wherein the protection circuit includes an inductive element coupling the first terminal of the capacitor with the bridge circuit, the switching element operable to electrically connect the first and second terminals together through the resistive and inductive elements to substantially dissipate the electrical energy in the resistive element, the inductive and resistive element together limiting a maximum voltage applied across the bridge circuit.

12. A circuit for producing a high energy pulse for application to a patient experiencing ventricular fibrillation, comprising:

- a storage circuit operable to store electrical energy;
- a steering circuit coupled with the storage circuit, the steering circuit adapted for coupling with the patient and operable to deliver the electrical energy from the storage circuit to the patient; and
- a disarm circuit coupled with the storage circuit and with the steering circuit, the disarm circuit operable to selectively shunt delivery of the electrical energy away from the steering circuit.

13. A circuit according to claim 12 wherein the disarm circuit includes a switching element and a resistive element, the switching element selectively electrically connecting the storage circuit with the resistive element to dissipate the electrical energy therein.

14. A circuit according to claim 13 wherein the switching element is a silicon-controlled rectifier.

15. A circuit according to claim 12 wherein the storage circuit includes a capacitor having first and second terminals and operable to store the electrical energy therebetween, wherein the steering circuit includes a bridge circuit coupled with the first and second terminals of the capacitor and operable to deliver a biphasic pulse of the electrical energy to the patient, and wherein the disarm circuit includes a series-connected switching element and resistive element coupled with the first and second terminals, the switching element operable to electrically connect the first and second terminals together through the resistive element to dissipate the electrical energy therein.

16. A circuit for producing a high energy pulse for application to a patient experiencing ventricular fibrillation, comprising:

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a storage circuit operable to store electrical energy;

a steering circuit coupled with the storage circuit, the steering circuit adapted for coupling with the patient and operable to deliver the electrical energy from the storage circuit to the patient; and

a limit circuit coupling the storage circuit with the steering circuit, the limit circuit operable to limit the delivery of the electrical energy from the storage circuit to the steering circuit.

17. A circuit according to claim 16 wherein the limit circuit includes a resistive element operable to limit current flow from the storage circuit to the steering circuit.

18. A circuit according to claim 16 wherein the limit circuit includes an inductive element operable to limit the time rate of change of current flow from the storage circuit to the steering circuit.

19. A circuit according to claim 16 wherein the storage circuit includes a capacitor having first and second terminals and operable to store the electrical energy therebetween, wherein the steering circuit includes a bridge circuit coupled with the first and second terminals of the capacitor and operable to deliver a biphasic pulse of the electrical energy to the patient, and wherein the limit circuit couples the first terminal of the capacitor with the bridge circuit and includes one of a resistive element and an inductive element respectively operable to limit the current flow and the time rate of change of the current flow from the capacitor to the bridge circuit.

20. A circuit for producing a high energy pulse for application to a patient experiencing ventricular fibrillation, comprising:

a storage circuit operable to store electrical energy;

a steering circuit coupled with the storage circuit, the steering circuit being adapted for coupling with the patient and operable to deliver the electrical energy from the storage circuit to the patient;

a disarm circuit coupled with the storage circuit and with the steering circuit and operable to selectively shunt delivery of the electrical energy away from the steering circuit; and

a limit circuit coupling the storage circuit with the steering circuit and operable to limit delivery of the electrical energy from the storage circuit to the steering circuit, the disarm circuit and limit circuit together operable to substantially limit a maximum voltage applied across the steering circuit.

21. A circuit according to claim 20 wherein the disarm circuit includes a series-connected switching element and a first resistive element, and wherein the limit circuit includes a second resistive element, the switching element operable to electrically connect the storage circuit to the first and second resistive elements to substantially dissipate the electrical energy therein, the first and second resistive elements forming a voltage divider to substantially limit the maximum voltage applied across the steering circuit.

22. A circuit according to claim 20 wherein the disarm circuit includes a series-connected switching element and a resistive element, and wherein the limit circuit includes an inductive element, the switching element operable to electrically connect the storage circuit to the resistive and inductive elements to substantially dissipate the electrical energy in the resistive element, the inductive and resistive element together limiting the maximum voltage applied across the bridge circuit.

23. A circuit according to claim 20 wherein the storage circuit includes a capacitor having first and second terminals

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and operable to store the electrical energy therebetween, wherein the steering circuit includes a bridge circuit coupled with the first and second terminals of the capacitor and operable to deliver a biphasic pulse of the electrical energy to the patient, wherein the protection circuit includes a series-connected switching element and a first resistive element shunting the bridge circuit, and wherein the protection circuit includes a second resistive element coupling the first terminal of the capacitor with the bridge circuit, the switching element operable to electrically connect the first and second terminals together through the first and second resistive elements to substantially dissipate the electrical energy therein, the first and second resistive elements forming a voltage divider to limit a maximum voltage applied across the bridge circuit.

24. A circuit according to claim 20 wherein the storage circuit includes a capacitor having first and second terminals and operable to store the electrical energy therebetween, wherein the steering circuit includes a bridge circuit coupled with the first and second terminals of the capacitor and operable to deliver a biphasic pulse of the electrical energy to the patient, wherein the protection circuit includes a series-connected switching element and a resistive element shunting the bridge circuit, and wherein the protection circuit includes an inductive element coupling the first terminal of the capacitor with the bridge circuit, the switching element operable to electrically connect the first and second terminals together through the resistive and inductive elements to substantially dissipate the electrical energy in the resistive element, the inductive and resistive element together limiting a maximum voltage applied across the bridge circuit.

25. A circuit for producing a high energy pulse for application to a patient experiencing ventricular fibrillation, comprising:

- a storage circuit having first and second terminals and operable to store electrical energy therebetween;
- a steering circuit coupled with the first terminal of the storage circuit, the steering circuit adapted for coupling with the patient and operable to deliver the electrical energy from the storage circuit to the patient;
- a disarm circuit coupled with the first and second terminals of the storage circuit, the disarm circuit operable to selectively shunt delivery of the electrical energy away from the steering circuit; and
- a switching circuit coupled with the steering circuit and with the second terminal of the storage circuit, the switching circuit operable to electrically connect and disconnect the steering circuit to and from the second terminal of the storage circuit to initiate and interrupt the delivery of electrical energy through the steering circuit, all respectively.

26. A circuit according to claim 25 wherein the switching circuit includes an electrically controlled switch having a node coupled with the steering circuit and with the disarm circuit, and wherein the disarm circuit is operable to provide a clamping voltage level to which the node is substantially clamped, thereby substantially limiting a maximum voltage applied across the switch.

27. A circuit according to claim 26 wherein the switch is an insulated gate bipolar transistor.

28. A circuit according to claim 26 wherein the node is a first node, and wherein the disarm circuit includes first and second series-connected resistors with a second node therebetween coupled with the first node and providing the clamping voltage level.

29. A circuit according to claim 25, further comprising a limit circuit coupling the first terminal of the storage circuit

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with the steering circuit, the limit circuit operable to limit the rate of delivery of the electrical energy from the storage circuit to the steering circuit.

30. A circuit according to claim 25, further comprising a voltage limiting circuit coupled with the switching circuit, the voltage limiting circuit operable to limit the voltage applied across the switching circuit to no more than a maximum voltage level.

31. In an electrical defibrillator for defibrillating a patient experiencing ventricular fibrillation, a method of delivering electrical energy to the patient, comprising the steps of:

- storing electrical energy;
- initiating delivery of the electrical energy to the patient;
- measuring an electrical value associated with the delivery; and
- if the measured electrical value falls within a predetermined range of acceptable values, then continuing delivery of the electrical energy to the patient; or
- if the measured electrical value does not fall within the range of acceptable values, the method then further comprising the steps of,
- interrupting delivery of the electrical energy to the patient; and
- discharging remaining stored electrical energy.

32. A method according to claim 31 wherein the step of measuring an electrical value includes the step of measuring a current value.

33. A method according to claim 31 wherein the step of measuring an electrical value includes the step of measuring a voltage value.

34. A method according to claim 31 wherein the step of interrupting delivery of the electrical energy to the patient includes the step of forming an electrical path shunting the patient, and wherein the step of discharging remaining stored electrical energy includes the step of substantially dissipating the remaining stored energy in the electrical path.

35. In an electrical defibrillator for defibrillating a patient experiencing ventricular fibrillation, a method of delivering electrical energy to the patient, comprising the steps of:

- storing electrical energy;
- initiating delivery of the electrical energy to the patient;
- limiting the delivery of the electrical energy;
- measuring an electrical value associated with the delivery; and
- if the measured electrical value falls within a predetermined range of acceptable values, then continuing delivery of the electrical energy to the patient; or
- if the measured electrical value does not fall within the range of acceptable values, the method then further comprising the steps of,
- interrupting delivery of the electrical energy to the patient; and
- discharging remaining stored electrical energy.

36. A method according to claim 35 wherein the step of limiting the delivery of the electrical energy includes the step of limiting electrical current.

37. A method according to claim 35 wherein the step of limiting the delivery of the electrical energy includes the step of limiting the time rate of change of electrical current.

38. A method according to claim 35 wherein the step of measuring an electrical value includes the step of measuring a current value.

39. A method according to claim 35 wherein the step of interrupting delivery of the electrical energy to the patient includes the step of forming an electrical path shunting the

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patient, and wherein the step of discharging remaining stored electrical energy includes the step of substantially dissipating the remaining stored energy in the electrical path.

40. In an electrical defibrillator having a storage circuit coupled with a steering circuit, the storage circuit for storing electrical energy and the steering circuit for directing the electrical energy to a patient, a method of delivering electrical energy to a patient, comprising the steps of:

charging the storage circuit to store electrical energy therein;

forming a first electrical path from the storage circuit to the patient through the steering circuit;

initiating delivery of the electrical energy via the first electrical path;

sensing the rate at which the electrical energy is delivered via the first path; and

if the rate falls within a predetermined acceptable range, then continuing to deliver the electrical energy via the first electrical path; or

if the rate does not fall within the acceptable range, the method then further comprising the steps of, forming a second electrical path from the storage circuit; and

opening the first electrical path.

41. A method according to claim 40 wherein the step of sensing the rate at which the electrical energy is delivered includes the step of sensing a current flow through the first electrical path.

42. A method according to claim 40 wherein the step of forming the second electrical path includes the step of forming an electrical path shunting the first electrical path.

43. A method according to claim 40 wherein if the rate does not fall within the acceptable range, the method further comprising the step of substantially dissipating the electrical energy in the second electrical path.

44. In an electrical defibrillator having a storage circuit coupled with a steering circuit, the storage circuit for storing electrical energy and the steering circuit for directing the electrical energy to a patient, a method of delivering electrical energy to a patient, comprising the steps of:

charging the storage circuit to store electrical energy therein;

forming a first electrical path from the storage circuit to the patient through the steering circuit;

initiating delivery of the electrical energy via the first electrical path;

limiting the delivery of the electrical energy;

sensing the rate at which the electrical energy is delivered via the first path; and

if the rate falls within a predetermined acceptable range, then continuing to deliver the electrical energy via the first electrical path; or

if the rate does not fall within the acceptable range, the method then further comprising the steps of, forming a second electrical path from the storage circuit; and

opening the first electrical path.

45. A method according to claim 44 wherein the step of limiting the delivery of the electrical energy includes the step of limiting electrical current.

46. A method according to claim 44 wherein the step of limiting the delivery of the electrical energy includes the step of limiting the time rate of change of electrical current.

47. A method according to claim 44 wherein the step of sensing the rate at which the electrical energy is delivered includes the step of sensing a current flow through the first electrical path.

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48. A method according to claim 44 wherein the step of forming the second electrical path includes the step of forming an electrical path shunting the first electrical path.

49. A method according to claim 44 wherein if the rate does not fall within the acceptable range, the method further comprising the step of substantially dissipating the electrical energy in the second electrical path.

50. In an electrical defibrillator having a storage circuit coupled with a steering circuit, the storage circuit for storing electrical energy and the steering circuit for directing the electrical energy to a patient, a method of delivering electrical energy to a patient, comprising the steps of:

storing electrical energy in the storage circuit;

initiating electrical current flow through the steering circuit; and

measuring a current magnitude of the electrical current flow through the steering circuit;

if the current magnitude falls within a predetermined acceptable range, then continuing to allow the electrical current flow through the steering circuit; or

if the current magnitude does not fall within the acceptable range, the method then further comprising the steps of,

forming an electrical path shunting the steering circuit;

controlling voltage applied across the steering circuit; and

stopping the electrical current flow through the steering circuit.

51. A method according to claim 50 wherein the step of controlling voltage applied across the steering circuit includes the step of limiting a maximum voltage applied across the steering circuit.

52. A method according to claim 50 wherein the step of controlling voltage applied across the steering circuit includes the step of limiting the time rate of change of the voltage applied across the steering circuit.

53. A method according to claim 50 wherein if the current magnitude does not fall within the acceptable range, the method further comprising the step of substantially dissipating remaining electrical energy stored in the storage circuit.

54. In an electrical defibrillator having a switching circuit coupling a storage circuit with a steering circuit, the storage circuit for storing electrical energy, the steering circuit for directing the electrical energy to a patient, and the switching circuit for initiating and stopping the transfer of electrical energy from the storage circuit to the steering circuit, a method of delivering electrical energy to a patient, comprising the steps of:

storing electrical energy in the storage circuit;

initiating electrical current flow through the steering circuit; and

measuring a current magnitude of the electrical current flow through the steering circuit;

if the current magnitude falls within a predetermined acceptable range, then continuing to allow the electrical current flow through the steering circuit; or

if the current magnitude does not fall within the acceptable range, the method then further comprising the steps of,

forming an electrical path shunting the steering circuit;

controlling voltage applied across the switching circuit; and

stopping the electrical current flow through the steering circuit.

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55. A method according to claim 54 wherein the step of controlling voltage applied across the switching circuit includes the step of limiting a maximum voltage applied across the switching circuit.

56. A method according to claim 54 wherein the step of controlling voltage applied across the switching circuit includes the step of limiting the time rate of change of the voltage applied across the switching circuit.

57. A method according to claim 54 wherein the step of controlling voltage applied across the switching circuit includes the steps of:

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producing a clamping voltage level in the electrical path shunting the steering circuit; and coupling the switching circuit to the clamping voltage level.

58. A method according to claim 54 wherein if the current magnitude does not fall within the acceptable range, the method further comprising the step of substantially dissipating remaining electrical energy stored in the storage circuit.

* * * * *

Exhibit H





US005773961A

United States Patent [19]
Cameron et al.

[11] **Patent Number:** **5,773,961**
 [45] **Date of Patent:** **Jun. 30, 1998**

[54] **DYNAMIC LOAD CONTROLLER FOR A BATTERY**

5,591,213 1/1997 Morgan 607/5

OTHER PUBLICATIONS

[75] **Inventors:** David B. Cameron, Seattle; Daniel J. Powers, Issaquah; Douglas H. Roberts, Bellevue, all of Wash.

Weaver et al. "Use of Automatic External Defibrillator in the Management of Out-of-Hospital Cardiac Arrest" 319 *N.E.J. Med.* 661 (1988).

[73] **Assignee:** Heartstream, Inc., Seattle, Wash.

Primary Examiner—Edward Tso

Attorney, Agent, or Firm—James R. Shayj; Cecily Anne Snyder

[21] **Appl. No.:** 659,503

[22] **Filed:** Jun. 6, 1996

[51] **Int. Cl.** **H01M 10/48**

[52] **U.S. Cl.** 320/132; 320/136; 320/DIG. 21; 607/5

[58] **Field of Search** 320/13, 15, 17, 320/20, 21, 22, 23, 32, 39, 43, 45, 48, 132, 136, DIG. 21; 324/427, 429; 340/636; 607/5, 29

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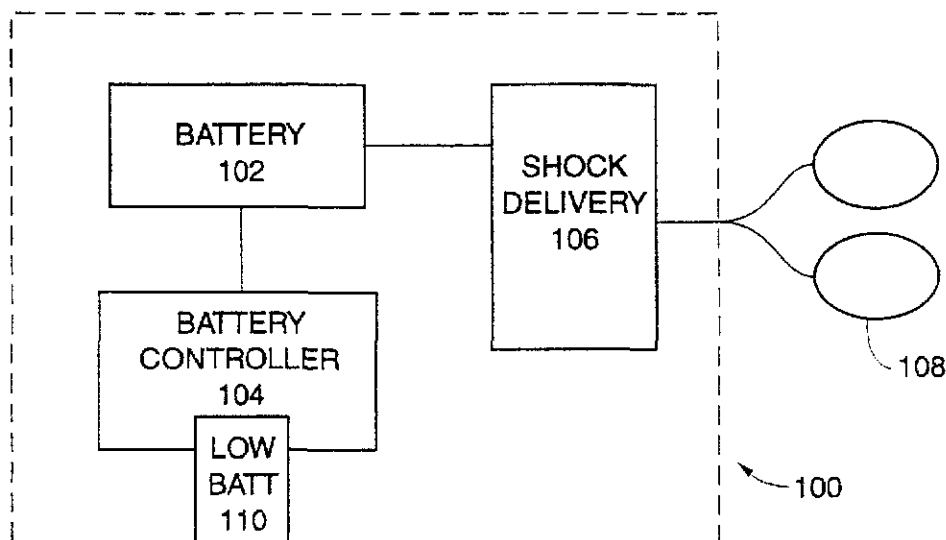
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[57] **ABSTRACT**

A method and apparatus for indicating a low battery condition and for dynamically controlling the load on a battery in order to optimize battery usage. A dynamic load controller for a battery includes detection circuitry for measuring at least one condition related to battery capacity, and power control circuitry for adjusting a power load on the battery based upon the condition. The dynamic load controller may be employed to control the power load on a battery that powers an electrotherapy device, such as a defibrillator. The battery condition may include the slope of a capacity curve, which may be the product of the battery voltage and the power delivered from the battery as a function of the delivered power. Based upon this condition, the power control circuitry adjusts the power load to optimize power delivery from the battery. The controller includes circuitry for indicating a low battery condition if battery voltage falls below a battery voltage threshold and the power load falls below a power threshold, or if the optimum power falls below a power threshold. The controller also includes circuitry for indicating a replace battery condition if battery voltage falls below a battery voltage threshold and the power load falls below a minimum power threshold, or if the optimum power falls below a minimum power threshold.

92 Claims, 9 Drawing Sheets



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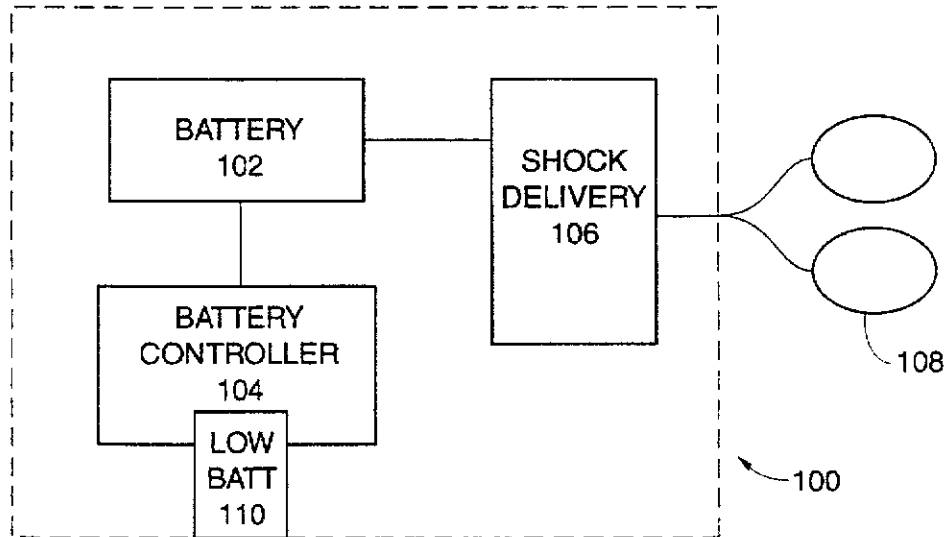


FIG. 1

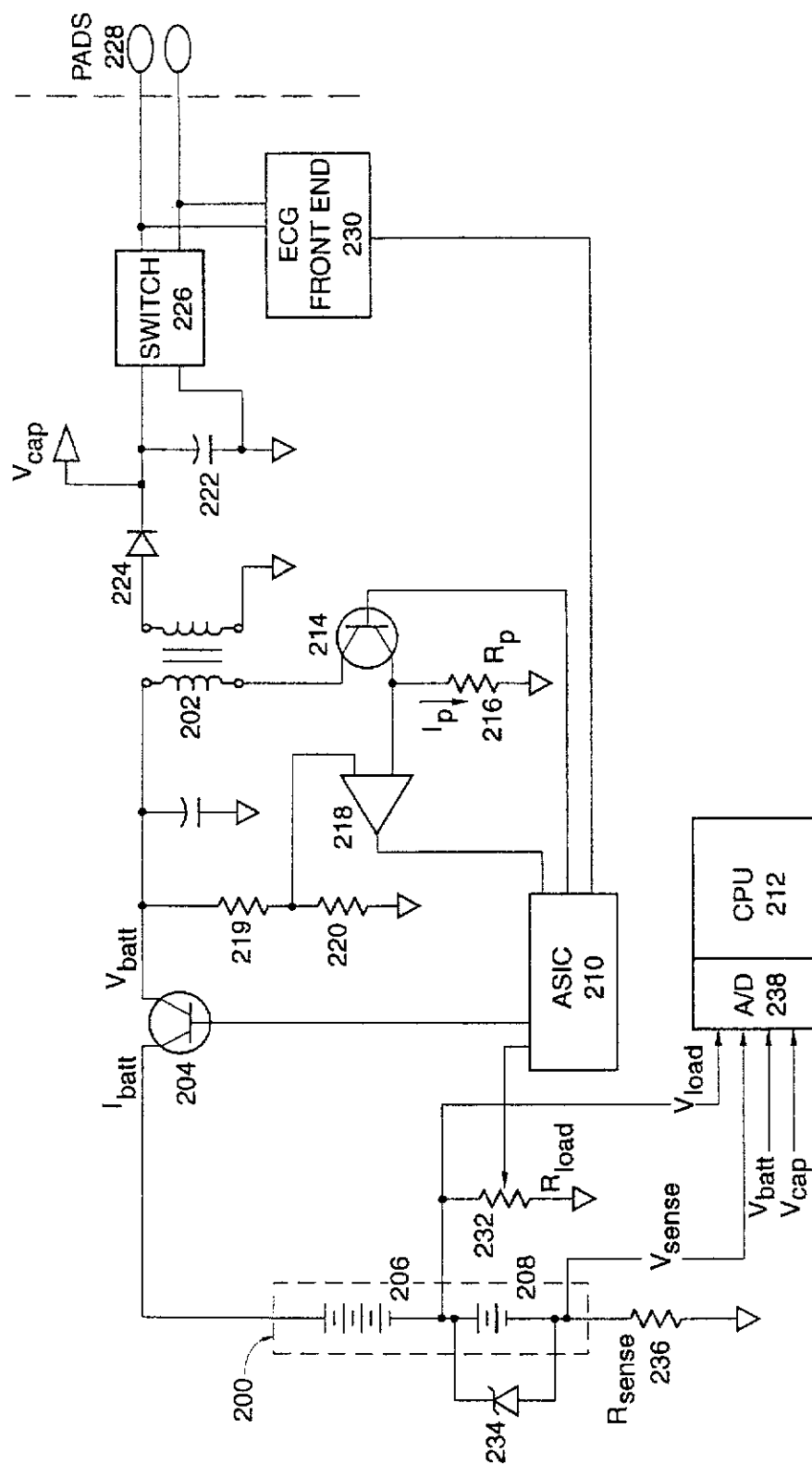


FIG. 2

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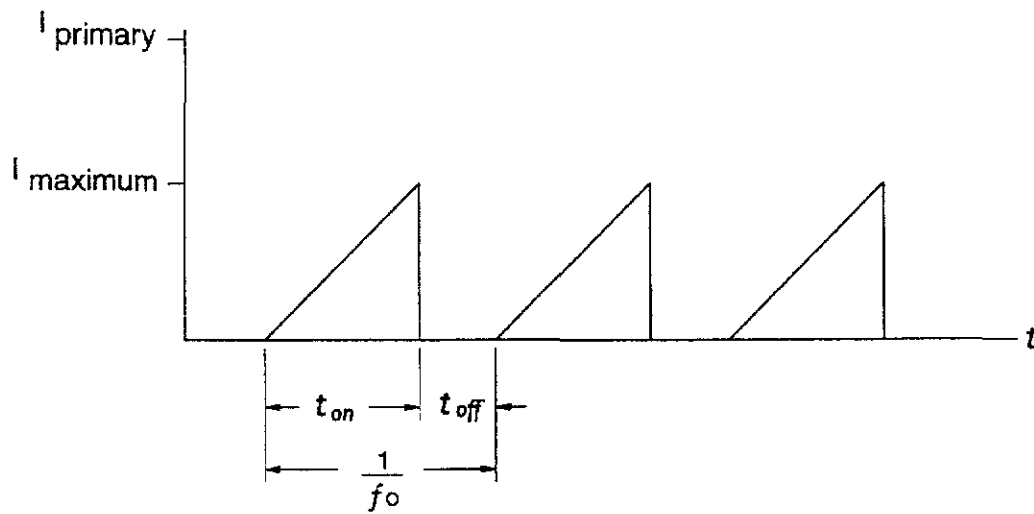


FIG. 3

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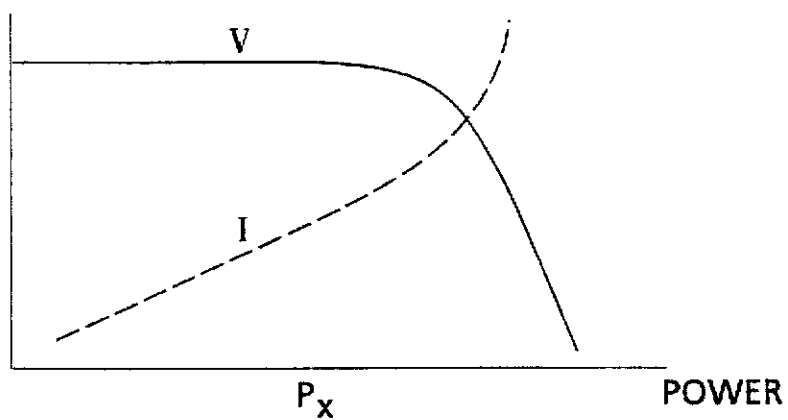


FIG. 4

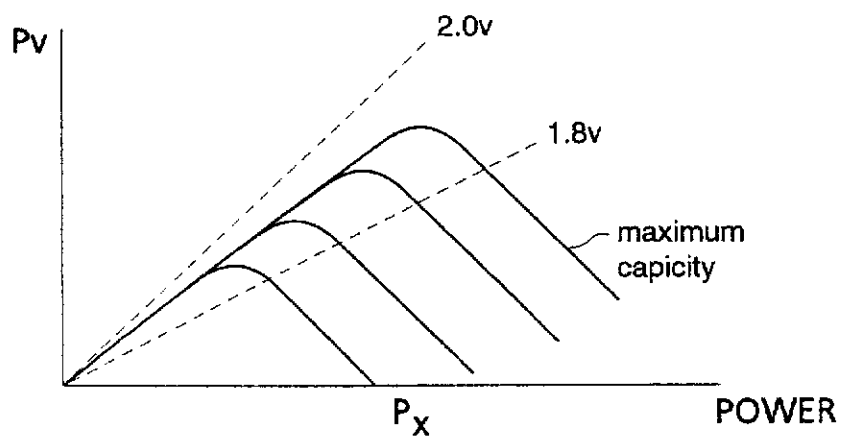


FIG. 5

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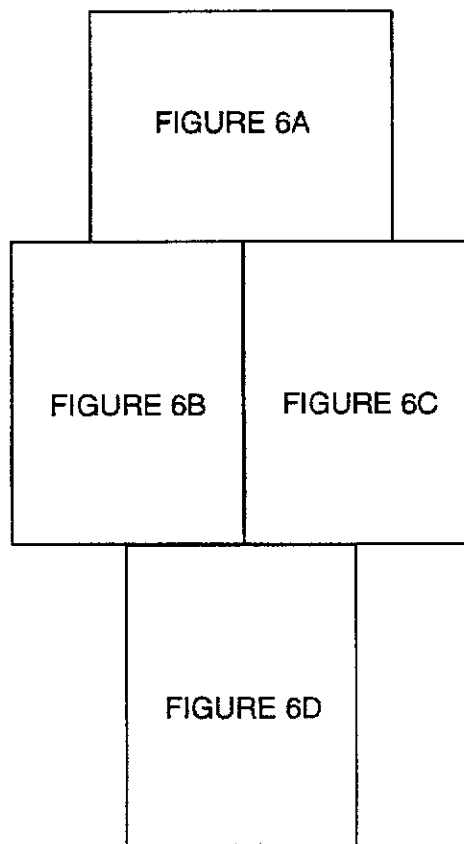
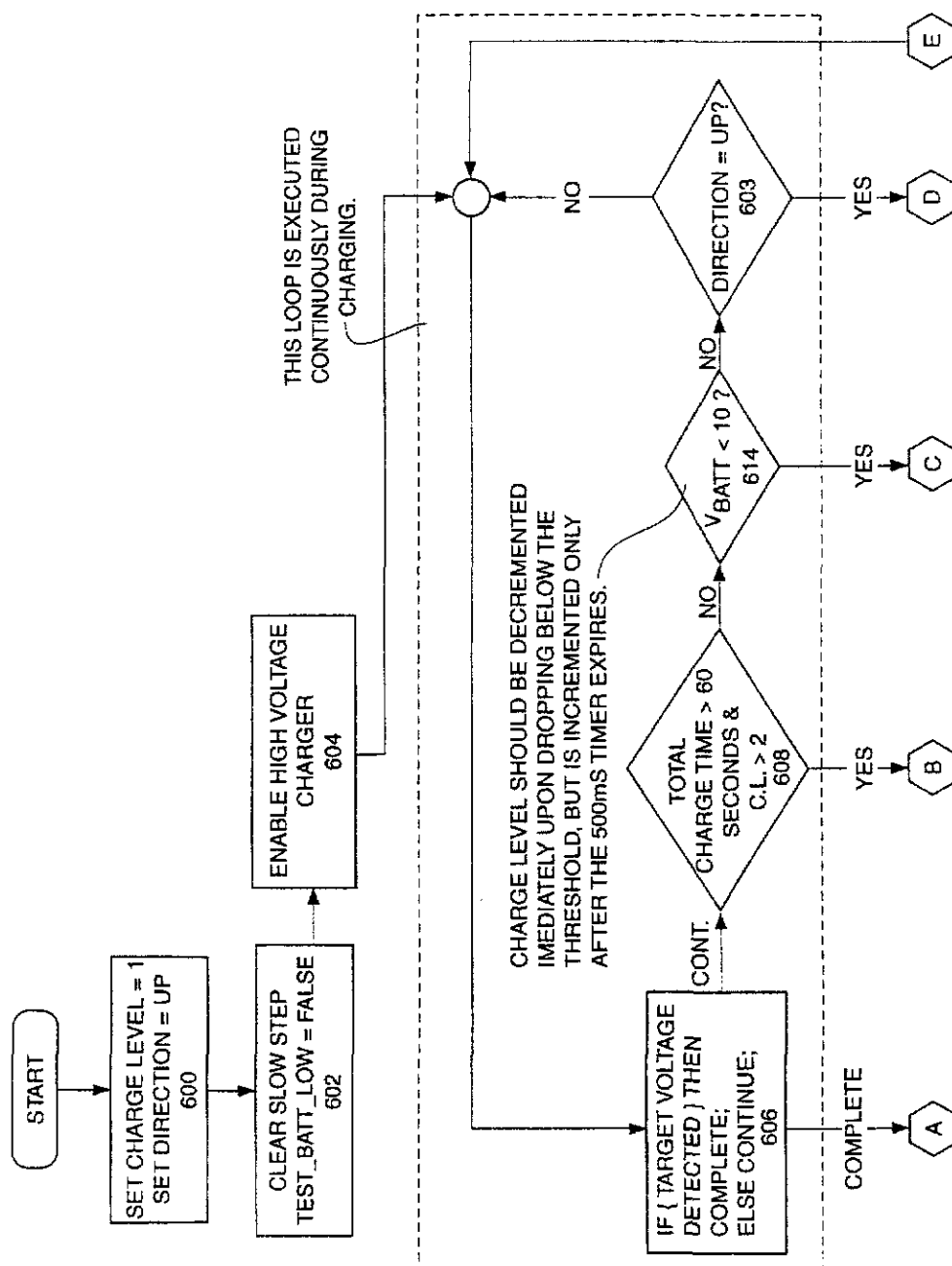


FIGURE 6



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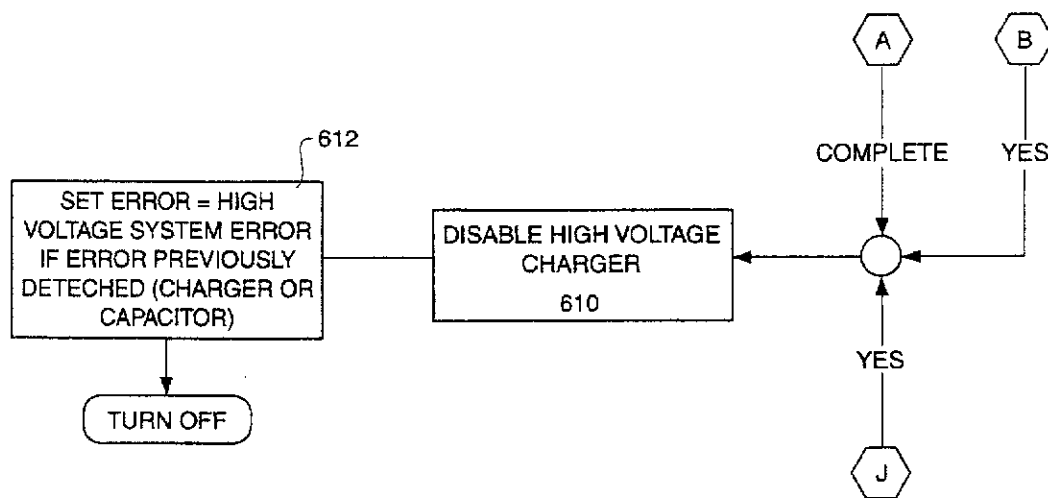


FIG. 6b

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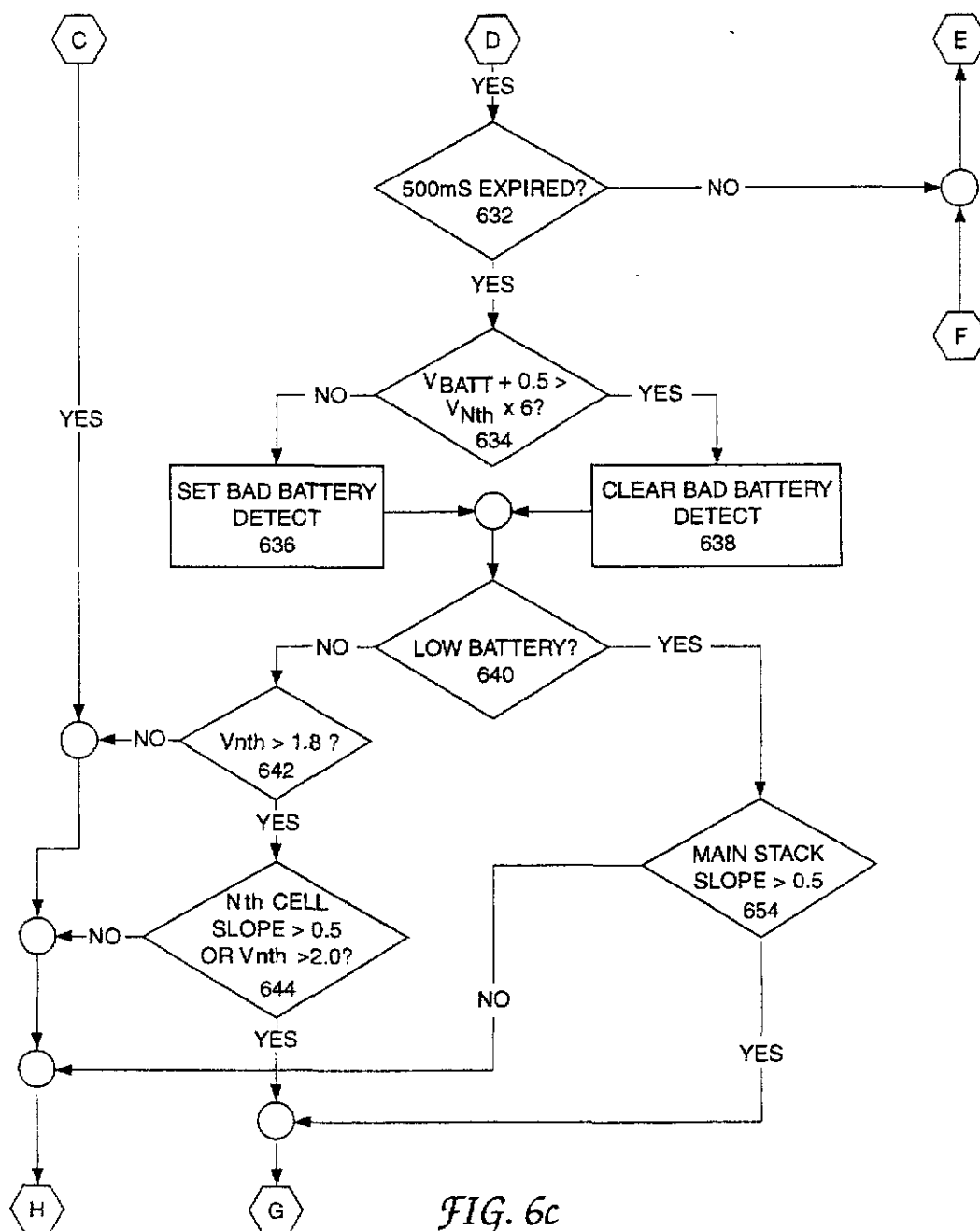


FIG. 6c

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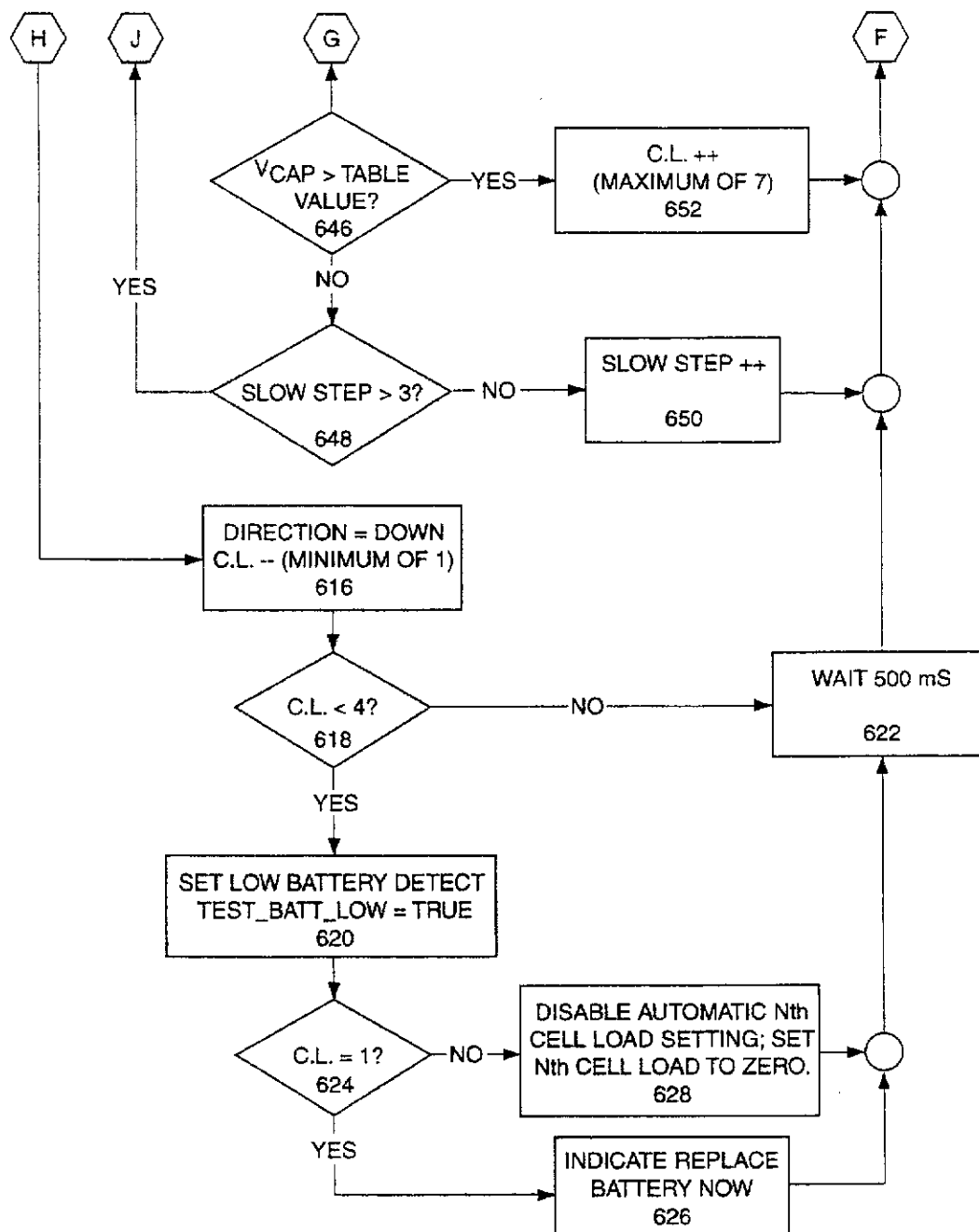


FIG. 6d

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DYNAMIC LOAD CONTROLLER FOR A BATTERY

FIELD OF THE INVENTION

The present invention relates to battery load controllers and battery capacity monitors generally and, in particular, to battery load controllers and battery capacity monitors for battery-operated electrotherapy devices and other battery-operated devices.

DESCRIPTION OF THE RELATED ART

When using a battery-operated device, it is often important to know when the useful life of the battery is about to end. For example, failure to indicate a low battery condition of a battery-operated computer could result in data loss if the remaining power is insufficient to save the information and exit the application. As another example, knowledge of the remaining battery capacity of a battery-operated medical device could be crucial in a medical emergency.

Electrotherapy devices are used to provide electric shocks to treat patients for a variety of heart arrhythmias. For example, external defibrillators provide relatively high-level shocks to a patient, usually through electrodes attached to the patient's torso, to convert ventricular fibrillation to a normal sinus rhythm. Similarly, external cardioverters can be used to provide shocks to convert atrial fibrillation to a more normal heart rhythm. Many electrotherapy devices are powered by batteries.

Prior art electrotherapy devices provide an indication of a low battery condition and a depleted battery condition. Stopping an electrotherapy treatment to replace a battery can have a detrimental effect on the patient being treated. None of the prior art electrotherapy devices, however, provides sufficient warning of an impending battery failure to allow an accurately predetermined minimum level or period of continued treatment before battery failure. For example, while a low battery warning on a prior art external defibrillator can mean that the battery has sufficient remaining capacity to provide one more treatment to a patient, it can also mean that the battery is so far depleted that no effective treatment is possible. The actual amount of battery capacity remaining when prior art devices indicate a low battery condition can vary with the ambient temperature, battery manufacturing variances, battery discharge history, battery recharge history, etc.

In addition, because batteries can be relatively large and heavy components of battery-operated devices (such as electrotherapy devices), it is important to use as much of the available battery capacity as possible before replacing the battery. It is also important to be able to control the battery's power delivery so that the device can be operated at an optimal level.

Batteries are rated according to a number of electrical characteristics, including voltage, capacity and acceptable current load. Within an acceptable temperature range and under acceptable load conditions, the battery is able to maintain its rated voltage. However, when heavily loaded, a battery can suffer a large drop in output voltage. The load at which this drop occurs relates to the remaining capacity of the battery.

These observations can be explained, in part, by reference to a simplified model of a battery. A battery system can be represented by a battery voltage source connected in series to an internal battery impedance that, in turn, is connected in series to a load impedance. Thus, the internal impedance in

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series with the load impedance acts as a voltage divider. Within limits, power to the load may be increased by decreasing the load impedance. As a result, the voltage drop across the load decreases while the voltage drop across the internal battery impedance increases. When battery capacity is low, internal battery impedance increases, thereby achieving a decrease in the voltage drop across the load. Under heavy loading, battery voltage decreases dramatically due to these and other electrochemical effects. In a more realistic system with a load that demands constant power, the battery current increases drastically as battery voltage drops to maintain constant power delivery to the load. Under sufficiently high loading conditions, this high current drain will cause a runaway condition in which current continues to rise, voltage continues to drop, and eventually power delivered to the load falls to zero.

To avoid this condition, most battery-operated systems simply maintain battery loading at a predetermined amount below a maximum acceptable power level. Typically, the battery is conservatively loaded so that a large, yet indeterminate amount of capacity remains before a low battery condition is indicated. By avoiding maximum drainage before indicating a low battery, such a system prevents battery shutdown as capacity diminishes. However, it is desirable to measure battery capacity more accurately so that the low battery indication occurs closer to actual battery depletion, and so that the remaining capacity can be estimated with greater certainty. Further, in some systems, it is desirable to deliver maximum power consistently to the load. For example, in a cardiac defibrillator, the power employed to charge an energy storage capacitor determines the speed with which the capacitor can be charged. This factor is thus especially important in life-saving situations as it affects charge time. Moreover, because the power load is typically fixed in such electrotherapeutic devices, the battery may approach shutdown as its capacity diminishes even though the battery may still store enough energy to provide effective electrotherapeutic treatment at lower power levels.

U.S. Pat. No. 5,483,165, issued to Cameron et al., and assigned to the assignee of the present invention (the disclosure of which is incorporated herein by reference) describes a battery system that can be used to provide an early indication of battery failure through the use of a sense cell in addition to the main battery. The '165 patent suggests that the sense cell can be related to the main battery such that when a sense cell parameter reaches a certain value the main battery has a predetermined remaining capacity. The '165 patent does not disclose, however, specific sense cell/main battery relationships for particular applications, nor does it address the issue of battery power control for the purpose of optimizing battery usage.

What is needed, therefore, is an instrument power system that has a battery load controller and/or a battery capacity monitor that provides an indication of a low battery condition early enough to be able to continue operating a battery-operated device at an optimal level for an effective period of time without calling for the replacement of the battery before the battery has been actually depleted.

SUMMARY OF THE INVENTION

To accomplish these and other objectives, the present invention provides a method and apparatus for indicating a low battery condition and for dynamically controlling the load on a battery in order to optimize battery usage. A dynamic load controller for a battery includes detection circuitry for measuring at least one condition related to

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battery capacity, and power control circuitry for adjusting a power load on the battery based upon the condition. The dynamic load controller may be employed to control the power load on a battery that powers an electrotherapy device, such as a defibrillator.

The battery condition may include the slope of a capacity curve, which may be the product of the battery voltage and the power delivered from the battery as a function of the delivered power. Based upon this condition, the power control circuitry adjusts the power load to optimize power delivery from the battery.

The controller includes circuitry for indicating a low battery condition if battery voltage falls below a battery voltage threshold and the power load falls below a power threshold, or if the optimum power falls below a power threshold. The controller also includes circuitry for indicating a replace battery condition if battery voltage falls below a battery voltage threshold and the power load falls below a minimum power threshold, or if the optimum power falls below a minimum power threshold.

In a battery system having a battery that includes a main stack for powering a main load and a sense cell for powering the main load and a dummy load, the controller may be employed to disable the dummy load based upon a battery condition. In this case, the optimization circuitry optimizes power delivery to the main load at an optimum power. The battery condition that triggers the disabling of the dummy load may be the optimum power falling below a power threshold, the battery voltage falling below a battery voltage threshold when power delivery to the main load falls below a power threshold, or the sense cell voltage falling below a sense cell voltage threshold when power delivery to the main load falls below a power threshold.

In this configuration, the controller may also include circuitry for indicating a low battery condition if the optimum power falls below a power threshold, the battery voltage falls below a battery voltage threshold when power delivery to the main load falls below a power threshold, or the sense cell voltage falls below a sense cell voltage threshold when power delivery to the main load falls below a power threshold. Further, the controller may include circuitry for indicating a replace battery condition if the optimum power falls below a minimum power threshold, the battery voltage falls below a battery voltage threshold when power delivery to the main load falls below a minimum power threshold, or the sense cell voltage falls below a sense cell voltage threshold when power delivery to the main load falls below a minimum power threshold.

Initially, the optimization circuitry optimizes power delivery to the main load at an optimum power level by measuring characteristics of the sense cell, and then optimizes power delivery to the main load by measuring characteristics of the main stack if the sense cell reaches a low capacity condition. This low capacity condition may occur when the sense cell voltage falls below a sense cell voltage threshold and power delivery to the main load falls below a power threshold, or when the optimum power level obtained by measuring sense cell characteristics falls below the power threshold.

In an electrotherapy device powered by a battery, the dynamic load controller may be used to provide a battery capacity indication by operating the electrotherapy device to treat a patient, monitoring a battery parameter during the operating step, and providing a low battery capacity indication based on a value of the battery parameter. The indication is provided while the electrotherapy device can

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provide at least three, six or nine electrical shocks to the patient under various timing constraints before the battery is depleted. When the electrotherapy device is operated to treat the patient, it may be used to deliver a shock to the patient and monitor the patient's ECG.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects, features and advantages of the present invention will be apparent to one skilled in the art in light of the following detailed description in which:

FIG. 1 is a block diagram of an electrotherapy device.

FIG. 2 illustrates a cardiac defibrillator incorporating an embodiment of a battery capacitor indicator and dynamic load controller of the present invention.

FIG. 3 illustrates a number of charging cycles of a flyback converter.

FIG. 4 illustrates voltage and current as a function of the power load on a battery.

FIG. 5 is a capacity curve plotting the product of power load and battery voltage against power load.

FIGS. 6 and 6A-6D are a flow chart illustrating the logic of the present invention employed to indicate low battery and depleted battery conditions and to control battery load dynamically in order to optimize power delivery.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a method and apparatus for providing an early indication of a low battery condition and/or for dynamically controlling the load on a battery. For purposes of explanation, specific details are set forth to provide a thorough understanding of the present invention. However, it will be understood by those skilled in the art, from reading this disclosure, that the invention may be practiced without these details. Moreover, well-known elements, devices, process steps and the like are not set forth in order to avoid obscuring the invention.

FIG. 1 is a block diagram of an electrotherapy device 100. Device 100 may be a defibrillator, a cardioverter, or any other electrotherapy device. The major components of device 100 are a battery 102, a battery capacity monitor/controller 104, and a shock delivery system 106 for delivering shocks to a patient through electrodes 108. The battery capacity monitor has a low battery capacity indicator 110 (such as a warning light, a display for text or images, an annunciator, etc.) for indicating when the remaining capacity of the battery falls below a threshold level. Device 100 may also include an optional patient monitor (not shown) for monitoring a condition of the patient.

During use of device 100 to treat a patient, battery 102 provides power to shock delivery system 106, and the shock delivery system uses this power to deliver electrical shocks through electrodes 108, as is known in the art. Battery controller 104 monitors a battery parameter related to the capacity of battery 102 during the treatment operation and provides an indication through low battery capacity indicator when a value of the monitored parameter indicates that the electrotherapy device has only a minimum capacity single use remaining before the battery is depleted. Battery controller 104 also controls the load applied to battery 102 in order to optimize the use of the remaining capacity of battery 102.

The definition of "minimum capacity single use" varies from application to application. For external defibrillators, for example, the minimum capacity single use may be

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defined as the ability to deliver at least three shocks at a therapeutic energy level to a patient, with the shock delivery system charging time for each shock being no greater than 60 seconds, most preferably no greater than 30 seconds. Three shocks in sequence have been shown to have a large cumulative probability of terminating cardiac fibrillation. See, e.g., Weaver, W. D., et al., "Use of the Automatic External Defibrillator in the Management of Out-of-Hospital Cardiac Arrest," 319 N.Eng.J.Med. 661 (Sep. 15, 1988). In some cases, however, the patient may not defibrillate after three shocks or may experience refrillation, thus requiring additional shock sequences. Few patients require more than three shock sequences.

Thus, in a preferred embodiment, the minimum capacity single use of an external defibrillator is the ability to deliver at least six truncated exponential biphasic waveform shocks (corresponding to two iterations of the three-shock protocol) of at least 130 Joules to a patient, with the shock delivery system shock to shock cycle time being no greater than 60 seconds (and most preferably no greater than 30 seconds), at a temperature of 0° C. In another preferred embodiment, the minimum capacity single use of an external defibrillator is the ability to deliver at least nine truncated exponential biphasic waveform shocks (corresponding to three iterations of the three-shock protocol) of at least 130 Joules to a patient, with the shock delivery system shock to shock cycle time being no greater than 60 seconds (and with the first six shocks preferably having a cycle time of 30 seconds or less), at a temperature of 0° C.

A preferred embodiment of the invention is described below with reference to an external defibrillator. It should be understood that the invention may also be applied to all electrotherapy devices and to other battery-operated devices as well.

FIG. 2 illustrates a cardiac defibrillator incorporating an embodiment of a battery capacity indicator and a dynamic load controller of the present invention. Those skilled in the art will understand that the battery capacity indicator and the dynamic load controller find applicability not just in defibrillators, but in a wide variety of battery-operated systems. Referring to FIG. 2, a battery 200 is switchably coupled to a primary coil of a flyback transformer 202 through an FET power switch 204. In one embodiment, the battery 200 may be a main stack 206 and sense cell 208 arrangement like that of U.S. Pat. No. 5,483,165. Those skilled in the art will recognize that the present invention is not limited to a main stack/sense cell arrangement, but rather is generally applicable to any battery system.

The power switch 204 is controlled by an application-specific integrated circuit (ASIC) 210 through commands provided by a CPU 212. The flyback converter circuitry of the defibrillator includes the ASIC 210, an FET flyback switch 214, a flyback current-sensing resistor 216, a comparator 218, and a voltage divider comprising a first resistor 219 and a second resistor 220.

The secondary coil of the flyback transformer 202 is coupled to an energy storage capacitor 222 through a diode 224 in order to charge the energy storage capacitor 222 to the target voltage. An energy transfer switch 226 transfers the charge from the energy storage capacitor 222 to defibrillator electrodes 228 that are applied to the patient's chest. The energy transfer switch 226 is typically actuated by the user. The defibrillator also includes an ECG front end 230 coupled to the electrodes, as is well known in the art.

As described in U.S. Pat. No. 5,483,165, the ASIC 210, acting as a controller, controls a programmable dummy load

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232 so that it draws an incremental current from the sense cell 208 in addition to the current passing through the main stack 206. This current is chosen to provide for a certain amount of remaining capacity in the main stack 206 after a drop in sense cell capacity indicates that the sense cell 208 has been depleted. In one preferred embodiment, for example, the incremental current is set at 25% over the current drawn from the main stack 206. Other examples are described below. A diode 234 permits the main stack 206 to be used after the sense cell has been depleted and prevents the sense cell from being electrically reversed.

A sense voltage V_{sense} is measured across a sense cell current-sensing resistor R_{sense} 236 and provided to an analog-to-digital converter (A/D) 238, which provides a digital representation of the voltage to the microprocessor 212. The CPU 212 calculates the current I_{sense} flowing through the sense cell 208 as

$$I_{sense} = \frac{V_{sense}}{R_{sense}}$$

Current that is related to (e.g., equal to, proportional to, or incrementally greater than) the current flowing through the main stack 206, I_{batt} , is drawn from the sense cell 208 by placing the programmable dummy load 232 R_{load} between the sense cell 208 and ground. Note that $I_{batt} = I_{sense}$ when the programmable load 232 is disabled.

The voltage drop V_{load} across the sense cell 208 and the sense cell current-sensing resistor 236 is also provided to the A/D 238. The microprocessor 212 calculates the voltage V_n across the sense cell 208 for use in calculations below according to the formula

$$V_n = V_{load} - V_{sense}$$

FIG. 3 illustrates a number of charging cycles of the flyback converter. During an on-time of a charging cycle, the ASIC 210 drives a voltage onto the gate of the flyback FET 214 to close the FET switch and charge the primary winding of the transformer 202. The primary current I_p increases linearly according to the relationship

$$\Delta I_p = \frac{V_p}{L_p} \Delta t$$

where L_p is the inductance of the primary and V_p is the voltage across the primary. One input of the comparator measures the voltage across the flyback current-sensing resistor R_p 216 to indirectly determine the current flowing through the primary coil. The voltage divider provides a voltage representing the maximum allowable primary current I_{max} . When the comparator 218 determines that the sensed current has reached I_{max} , it issues a signal to the ASIC 210. In response, the ASIC 210 opens the FET flyback switch 214 to stop charging of the primary. At this point, the on-time ends and the off-time of the charging cycle begins. When the on-time ends, the collapsing field in the primary develops current in the secondary winding, which charges the high-energy capacitor 222.

The present invention recognizes that the energy delivered to the primary during one charging cycle may be represented by the following equation

$$E = \frac{1}{2} L_p I_{max}^2$$

and that the power delivered during a charging cycle may be represented as

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$$P = \frac{1}{2} f_0 L_p I_{max}^2$$

where T , the period of a charging cycle, is the total of the on-time and the off-time, and $f_0 = 1/T$. The inductance L_p , the maximum allowable primary current I_{max} , and the desired power P are all known variables. Therefore, solving for f_0 ,

$$f_0 = \frac{2P}{L_p I_{max}^2}$$

Based upon this equation, the CPU 212, through the ASIC 210, controls the switching frequency of the flyback FET switch 214 in order to control the power delivered to the primary coil of the transformer 202. The switching frequency is limited by the minimum allowable T that avoids overlap of the on-times of subsequent charging cycles. Based upon limiting I_p to I_{max} ,

$$\min(t_{on}) = \frac{L_p}{V_p} I_{max}$$

The CPU calculates V_p as the battery voltage V_{batt} less V_{sense} , the voltage across the flyback current-sensing resistor 216 and the known voltage drop across the flyback FET 214.

Similarly, for the off-time,

$$\min(t_{off}) = \frac{L_s}{V_s} I_{max}$$

where the secondary voltage V_s is the capacitor 222 voltage V_{cap} plus secondary voltage losses (nominally 10 volts), and the secondary current I_{smax} is related to the primary current in a well known manner. The highest frequency that the CPU 212 will request is based upon the worst case on and off-times. Note that as the capacitor 222 is charged, V_s increases, and the off-time will decrease, allowing the switching frequency to increase with time.

FIG. 4 illustrates voltage and current as a function of the power load on a lithium battery. Those skilled in the art will recognize that the present invention is not limited to lithium batteries. Further, for the sake of convenience, the voltage curve will also be referred to as a "capacity curve." The capacity curve exhibits a dramatic drop in voltage when load power exceeds an acceptable maximum power P_x . To maintain constant power to the load, the current must conversely increase drastically to offset the decrease in voltage. At some point, the current will increase to a value that will lead to battery failure. Thus, this curve cannot provide an accurate measure of battery capacity because increasing power to take measurements near P_x risks battery failure. Accordingly, conventional battery-operated devices typically limit the load so that the power drawn from the battery lies in the region well below P_x , and indicates a low battery well before actual depletion. This mode of operation is acceptable for many applications. However, for some applications, such as cardiac defibrillators, it is preferred to maximize power delivery without causing battery failure. Further, it is generally desired to measure battery capacity more accurately. Accurate measurement permits a low battery warning to be indicated with the assurance that a predetermined battery capacity remains thereafter.

To accomplish these objectives, one embodiment of the present invention adjusts the power load on the battery as a function of the slope of the capacity curve so that it is operating near the knee of the curve of FIG. 4, i.e., at a maximum acceptable power level. The slope of the curve is relatively flat until P_x , at which point it begins to turn sharply

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negative. When the slope falls below a predetermined negative slope threshold value, the CPU, through the ASIC, decreases f_0 to lower the power load on the battery so that it is again operating in a safe operating region. One difficulty with this technique is determining the proper slope threshold value. The appropriate slope threshold for a particular battery varies as a function of a number of factors, including capacity, rated voltage and temperature.

Accordingly, the present invention employs the improved capacity curve of FIG. 5 to overcome this problem. FIG. 5 plots the product of power load and battery voltage against power load. A family of curves is illustrated for different battery capacities. For these curves, the optimum power loading condition occurs at the maximum of each curve. At power levels below the maximum, the slope is essentially the same as the voltage because the voltage is substantially flat below P_x . However, for power levels above P_x , the voltage falls sharply at a rate faster than the increase in power, thereby causing the product PV to also have a negative slope for power levels above P_x . In this embodiment, P_x occurs when the slope is zero, regardless of battery type, capacity, temperature or other environmental conditions. Accordingly, the capacity curve of FIG. 5 is a much more robust measure of optimum power, which is also easier to implement.

The capacity curve of FIG. 5 is preferably employed in a main stack/sense cell arrangement, such as that shown in FIG. 2. The dynamic load controller first optimizes power delivery for the sense cell using a sense cell capacity curve $V_n I_{sense}$ as a function of $V_n I_{sense}$. As the sense cell becomes depleted and falls below a predetermined capacity, then the dynamic load controller optimizes power delivery based upon a battery capacity curve $V_{batt}^2 I_{batt}$ as a function of $V_{batt} I_{batt}$. Those skilled in the art will recognize that use of the capacity curve of the invention is generally applicable to any battery system.

FIG. 6 is a flow diagram illustrating the logic implemented by the CPU and the ASIC to indicate low battery conditions and to control battery load dynamically in order to optimize power delivery in the defibrillator of FIG. 2. The logic initially sets charge level=1 (by adjusting f_0) and a direction flag to UP to indicate that charge level is to be increased (step 600). Table 1 illustrates the relationship between charge level and input power to the primary coil of the transformer.

TABLE 1

CHARGE LEVEL	CHARGER POWER (W)
1	5
2	7.5
3	10
4	12.5
5	15
6	17.5
7	20

The logic then clears a counter SLOW STEP (step 602) and enables the high-voltage charger of the defibrillator by starting to switch the flyback FET switch 214 at the switching frequency (step 604). The logic then determines whether charging is complete by determining whether the capacitor voltage has reached a target voltage (step 606). If not, then, during charging, the logic determines whether the total charge time exceeds a predetermined time threshold (here, 60 seconds) when the charge level is above a predetermined charge level threshold (here, 2) (step 608). These thresholds

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are selected so that the system knows that a hardware error has occurred because, at charge levels above the charge level threshold, charging should take less time than the predetermined time threshold. In case of a hardware error, the high-voltage charger is disabled (step 610) and a system error is registered (step 612).

The logic also test whether the total battery voltage V_{batt} is less than a battery voltage threshold (here, 10 volts) (step 614). If it is, then the logic sets the charge direction flag to the DOWN state, and decrements the charge level (step 616). The logic then determines whether, at this low battery voltage, the battery can maintain power above a predetermined power threshold (step 618). In this example, the logic sets a LOW BATTERY DETECT (test batt low) flag if the charge level is less than 4 (step 620). If, on the other hand, the charge level equals or exceeds the power threshold, then the logic waits a half-second after decrementing the charge level (step 622) to allow the battery voltage to recover for the next test at step 606. The invention allows a "dwell time" (a half-second in this example) for the battery voltage to settle after adjusting power levels before conducting any battery measurements. By allowing the charge level to be decreased, the load controller provides an advantage over prior art fixed-load systems in which the battery is loaded more heavily at lowered capacity than necessary, which leads to a low battery indication when the battery may still be able to deliver effective electrotherapeutic treatment under lighter loading conditions.

In the case that the LOW BATTERY DETECT flag is set, the logic continues to test the charge level to determine whether it is below a minimum power threshold (step 624). In this example, if the charge level is less than 2 (C.L.-1), this indicates that the battery has been depleted, and the logic indicates that battery replacement is necessary (steps 626). If, on the other hand, the minimum power threshold is exceeded, then the logic disables the sense cell loading in order to provide extra capacity to the battery as a whole (step 628). The logic continues at step 622.

Returning to step 614, if, on the other hand, the battery voltage equals or exceeds the battery voltage threshold (10 volts), then the logic determines whether the direction flag is set to UP (step 630). Assuming that charge direction is initially UP, the logic determines whether a half-second has expired since the last time the charge level was adjusted (step 632).

After a half-second has passed, the logic determines whether the total battery voltage is too low based upon a measurement of the sense cell voltage (step 634). In the preferred embodiment, the battery comprises six identical cells including the main stack and the sense cell, otherwise known as the n th cell. If the total battery voltage V_{batt} falls below $6V_n - 0.5$ (a small voltage margin), then the logic sets a flag indicating a bad battery (step 636). If not, then the logic clears any bad battery flag that may have been set during a previous charge cycle (step 638). This is one way in which the sense cell helps determine whether the main stack has been depleted.

The logic then determines whether the LOW BATTERY flag has been set (step 640). If not, the logic determines whether the sense cell voltage, V_n , is greater than a predetermined low-voltage threshold (step 642). Here, the threshold=1.8 volts. The threshold is selected as the voltage at which the cell has been substantially depleted. If the cell voltage is satisfactory, then the logic determines whether the slope of the FIG. 5 capacity curve for the sense cell is greater than a predetermined slope threshold or whether the sense cell voltage is greater than a predetermined high-voltage

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threshold (here 2 volts) (step 644). The sense cell slope, m_n , is calculated by the logic as follows:

$$m_n = \frac{V1^2 \times I1 - V2^2 \times I2}{V1 \times I1 - V2 \times I2}$$

where $V1=V_n$, $I1=I_{sense}$ for the current power setting, and $V2=V_n$, $I2=I_{sense}$ for the previous setting.

The predetermined slope threshold is selected to be near zero, i.e., the curve maximum, yet slightly greater than zero to ensure that the load power is not set to a value greater than P_x . At power levels greater than P_x , the voltage would drop drastically, possibly leading to battery failure. Here, the predetermined slope threshold is preferably selected as 0.5. A slope greater than the slope threshold thus indicates that the charge level need not be decreased in order to avoid battery failure, and that an attempt should be made to increase charge level in order to achieve optimal power delivery. Similarly, a sense cell voltage greater than the high-voltage threshold indicates a healthy sense cell for which an attempt should be made to increase the power load.

Before allowing the charge level to be increased, one embodiment of the present invention first compares the capacitor voltage to the capacitor voltage thresholds shown in Table 2 depending upon the current charge level (step 646).

TABLE 2

CHARGE LEVEL	VOLTAGE
1	117.4
2	186.5
3	258.9
4	310.0
5	360.8
6	444.6
7	N/A

The capacitor voltage thresholds for a particular charge level are calculated to assure that the capacitor voltage is high enough so that the input power to the primary can be incremented by a power increment and still allow sufficient time for the secondary winding to discharge completely into the capacitor before starting the next charging cycle. The values shown in the table correspond to charge level increments of 2.5 watts, as shown in Table 1, a 100 microfarad energy storage capacitor, and a dwell time of a half-second. If the capacitor voltage is not greater than the corresponding capacitor voltage threshold, then the logic increments a counter SLOW STEP to indicate that charging will occur too slowly. If, after a number of dwell time periods (here, a number greater than 3), the defibrillator is still incrementing the SLOW STEP counter, then the logic will disable the high-voltage charger and register a system error (steps 648, 650, 610, 612).

If, on the other hand, the capacitor voltage exceeds the corresponding capacitor voltage threshold, then the charge level is incremented by 1 (step 652), and the logic increases the frequency at which the FET switch is operated to achieve the corresponding power level. The logic continues with step 606.

Returning to steps 642, 644, if these sense cell conditions are negative, then the logic sets the direction flag in the DOWN direction, decrements the charge level (step 616), and performs the steps that follow in the flowchart in a manner similar to the case where the battery voltage fell below the battery voltage threshold.

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If the LOW BATTERY DETECT flag is set due to a condition of the sense cell (step 620), then this indicates that the sense cell is nearly depleted, and that power should be optimized with respect to the battery as a whole. Accordingly, the logic determines whether the slope of the capacity curve for the battery exceeds a predetermined battery slope threshold (here, 0.5) (step 654). The battery slope is calculated as

$$m_{\text{bat}} = \frac{V1^2 \times I1 - V2^2 \times I2}{V1 \times I1 - V2 \times I2}$$

where $V1 = V_{\text{bat}}$, $I1 = I_{\text{bat}}$ for the current power setting, and $V2 = V_{\text{bat}}$, $I2 = I_{\text{bat}}$ for the previous setting. Note that $I_{\text{bat}} = I_{\text{sense}}$ at this point because the dummy load has been disabled.

If the battery slope is greater than the slope threshold, then the logic proceeds with step 646, which may result in an increase of charge level. If not, then the logic proceeds to step 616 to decrease the charge level. In this manner, the power level is optimized for the battery with respect to the battery capacity curve. Note that charge level for either the sense cell or the whole battery is never decremented more than once during a dwell time period.

The logic performs this optimization function with respect to the sense cell and the main stack until the logic detects that the voltage on the capacitor has reached a target voltage (step 606). If so, then the charging process is complete, and no more charging cycles are required.

Referring back to the first embodiment of FIG. 4 for determining optimum power level, the flow chart of FIG. 6 may employ the curve of FIG. 4 by substituting a comparison of the FIG. 5 capacity curve slope with a comparison of the FIG. 4 slope to a different slope threshold. That slope threshold would indicate that power cannot be increased when the slope begins to become negative. At that point, the charge level must be decremented.

The invention may be used to provide the ability to deliver a minimum capacity single use when a low battery condition is indicated. The following examples illustrate specific applications of the invention to external defibrillators.

EXAMPLE 1

An external defibrillator was constructed and operated according to the apparatus of FIG. 1 and the logic of FIG. 5, to deliver a 245 Joule truncated exponential biphasic waveform shock. The test was run at 0° C.

A new 80,000 Joule battery was placed in the defibrillator, and the defibrillator was operated to deliver one shock every 15 minutes during ECG monitoring, until the "Low Battery" warning appeared. I_{sense} was controlled to be 20% greater than I_{bat} throughout. Use of the defibrillator then ceased for one hour.

Next, the defibrillator was operated in an end use mode providing groups of three shocks (spaced one minute apart) during a total of five minutes of monitoring. 28,539 Joules were extracted from the battery in the end use mode before the "Low Battery" warning appeared. Thereafter, the battery provided 18,868 Joules until the "Replace Battery" warning appeared. During this final period from "Low Battery" to "Replace Battery," the defibrillator delivered 41 shocks requiring a 60-second charge time (or less). Of these 41 shocks, 32 shocks required less than 30 seconds of charge time.

EXAMPLE 2

This test was performed using an external defibrillator substantially the same as in Example 1 to deliver 245 Joule truncated exponential waveform shocks. The test was run at 25° C.

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A new 80,000 Joule battery was placed in the defibrillator, and the defibrillator was operated to deliver one shock every 15 minutes during ECG monitoring, until the "Low Battery" warning appeared. In this example, however, I_{sense} was controlled to be 30% greater than I_{bat} throughout. Use of the defibrillator then ceased for one hour.

Next, the defibrillator was operated in an end use mode providing groups of three shocks (spaced one minute apart) during a total of five minutes of monitoring. 54,451 Joules were extracted from the battery in the end use mode before the "Low Battery" warning appeared. Thereafter, the battery provided 10,573 Joules until the "Replace Battery" warning appeared. During this final period from "Low Battery" to "Replace Battery," the defibrillator delivered 23 shocks requiring a 60-second charge time (or less). Of these 23 shocks, 20 shocks required less than 30 seconds of charge time.

EXAMPLE 3

This test was performed using an external defibrillator substantially the same as in Example 1 to deliver 245 Joule truncated exponential waveform shocks. The test was run at 25° C.

A new 80,000 Joule battery was placed in the defibrillator, and the defibrillator was operated to deliver shocks in groups of fifteen (with no monitoring), followed by 30 minutes of inactivity, until the "Low Battery" warning appeared. I_{sense} was controlled to be 20% greater than I_{bat} throughout. Use of the defibrillator then ceased for one hour.

Next, the defibrillator was operated in an end use mode providing groups of three shocks (spaced one minute apart) during a total of five minutes of monitoring. 47,809 Joules were extracted from the battery in the end use mode before the "Low Battery" warning appeared. Thereafter, the battery provided 7371 Joules until the "Replace Battery" warning appeared. During this final period from "Low Battery" to "Replace Battery," the defibrillator delivered 16 shocks requiring a 60-second charge time (or less). Of these 16 shocks, 13 shocks required less than 30 seconds of charge time.

EXAMPLE 4

This test was performed using an external defibrillator substantially the same as in Example 1 to deliver 245 Joule truncated exponential waveform shocks. The test was run at 0° C.

A new 80,000 Joule battery was placed in the defibrillator, and the defibrillator was operated to deliver shocks in groups of fifteen (with no monitoring), followed by 30 minutes of inactivity, until the "Low Battery" warning appeared. I_{sense} was controlled to be 30% greater than I_{bat} throughout. Use of the defibrillator then ceased for one hour.

Next, the defibrillator was operated in an end use mode providing groups of three shocks (spaced one minute apart) during a total of five minutes of monitoring. 20,355 Joules were extracted from the battery in the end use mode before the "Low Battery" warning appeared. Thereafter, the battery provided 20,213 Joules until the "Replace Battery" warning appeared. During this final period from "Low Battery" to "Replace Battery," the defibrillator delivered 44 shocks requiring a 60-second charge time (or less). Of these 44 shocks, 38 shocks required less than 30 seconds of charge time.

All references cited herein are incorporated by reference herein in their entirety. Further, it will be appreciated that

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various modifications and alterations might be made by those skilled in the art without departing from the spirit and scope of the present invention. The invention should, therefore, be measured in terms of the claims which follow.

What is claimed is:

1. A dynamic load controller for a battery, comprising:
detection circuitry for measuring at least one condition related to battery capacity; and
optimization circuitry for optimizing power delivery from the battery at an optimum power based upon the at least one condition.
2. The dynamic load controller of claim 1, wherein the at least one condition is a slope of a capacity curve of the battery.
3. The dynamic load controller of claim 2, wherein the capacity curve is the product of the battery voltage and the power delivered from the battery as a function of the power delivered from the battery.
4. The dynamic load controller of claim 1, further comprising circuitry for indicating a low battery condition if the optimum power falls below a power threshold.
5. The dynamic load controller of claim 1, further comprising circuitry for indicating a replace battery condition if the optimum power falls below a minimum power threshold.
6. The dynamic load controller of claim 1, wherein the battery powers an electrotherapy device.
7. A dynamic load controller for a battery, comprising:
detection circuitry for measuring at least one condition related to battery capacity; and
power control circuitry for adjusting a power load on the battery based upon the at least one condition, wherein the at least one condition includes a slope of a capacity curve of the battery.
8. The dynamic load controller of claim 7, further comprising circuitry for indicating a low battery condition if battery voltage falls below a battery voltage threshold and the power load falls below a power threshold.
9. The dynamic load controller of claim 7, further comprising circuitry for indicating a replace battery condition if battery voltage falls below a battery voltage threshold and the power load falls below a minimum power threshold.
10. The dynamic load controller of claim 7, wherein the power control circuitry adjusts the power load to optimize power delivery from the battery.
11. The dynamic load controller of claim 7, wherein the capacity curve is the product of battery voltage and the power load on the battery as a function of the power load.
12. The dynamic load controller of claim 10, further comprising circuitry for indicating a low battery condition if the optimum power falls below a power threshold.
13. The dynamic load controller of claim 10, further comprising circuitry for indicating a replace battery condition if the optimum power falls below a minimum power threshold.
14. The dynamic load controller of claim 7, wherein the battery powers an electrotherapy device.
15. In a battery system having a battery that includes a main stack for powering a main load and a sense cell for powering the main load and a dummy load, a dynamic load controller comprising:
detection circuitry for measuring at least one condition of the battery; and
disabling circuitry for disabling the dummy load based upon the at least one condition of the battery.
16. The dynamic load controller of claim 15, further comprising optimization circuitry for optimizing power delivery to the main load at an optimum power.

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17. The dynamic load controller of claim 16, wherein the at least one condition is the optimum power falling below a power threshold.

18. The dynamic load controller of claim 16, wherein the optimization circuitry optimizes power based upon a slope of a capacity curve of the battery.

19. The dynamic load controller of claim 13, wherein the capacity curve is the product of battery voltage and the power delivered to the main load as a function of the power delivered to the main load.

20. The dynamic load controller of claim 15, wherein the at least one condition is the battery voltage falling below a battery voltage threshold and power delivery to the main load falling below a power threshold.

21. The dynamic load controller of claim 15, wherein the at least one condition is the sense cell voltage falling below a sense cell voltage threshold and power delivery to the main load falling below a power threshold.

22. The dynamic load controller of claim 16, further comprising circuitry for indicating a low battery condition if the optimum power falls below a power threshold.

23. The dynamic load controller of claim 16, further comprising circuitry for indicating a replace battery condition if the optimum power falls below a minimum power threshold.

24. The dynamic load controller of claim 15, further comprising circuitry for indicating a low battery condition if the battery voltage falls below a battery voltage threshold and power delivery to the main load falls below a power threshold.

25. The dynamic load controller of claim 15, further comprising circuitry for indicating a low battery condition if the sense cell voltage falls below a sense cell voltage threshold and power delivery to the main load falls below a power threshold.

26. The dynamic load controller of claim 15, further comprising circuitry for indicating a replace battery condition if the battery voltage falls below a battery voltage threshold and power delivery to the main load falls below a minimum power threshold.

27. The dynamic load controller of claim 15, further comprising circuitry for indicating a replace battery condition if the sense cell voltage falls below a sense cell voltage threshold and power delivery to the main load falls below a minimum power threshold.

28. The dynamic load controller of claim 15, wherein the battery powers an electrotherapy device.

29. In a battery system having a battery that includes a main stack for powering a main load and a sense cell for powering the main load and a dummy load, a dynamic load controller comprising:

circuitry for optimizing power delivery to the main load at an optimum power level by measuring characteristics of the sense cell; and

circuitry for optimizing power delivery to the main load by measuring characteristics of the main stack if the sense cell reaches a low capacity condition.

30. The dynamic load controller of claim 29, wherein the low capacity condition comprises the sense cell voltage falling below a sense cell voltage threshold and power delivery to the main load falling below a power threshold.

31. The dynamic load controller of claim 29, wherein the low capacity condition comprises the optimum power level falling below a power threshold.

32. The dynamic load controller of claim 29, wherein the optimizing circuitry includes circuitry for adjusting power delivery based in part upon a slope of a capacity curve of the battery.

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33. The dynamic load controller of claim 29, wherein the battery powers an electrotherapy device.

34. A method for dynamically controlling the load on a battery, comprising the steps of:

measuring at least one condition related to battery capacity; and

optimizing power delivery from the battery at an optimum power based upon the at least one condition.

35. The method of claim 34, wherein the at least one condition is a slope of a capacity curve of the battery.

36. The method of claim 35, wherein the capacity curve is the product of the battery voltage and the power delivered from the battery as a function of the power delivered from the battery.

37. The method of claim 34, further comprising the step of indicating a low battery condition if the optimum power falls below a power threshold.

38. The method of claim 34, further comprising the step of indicating a replace battery condition if the optimum power falls below a minimum power threshold.

39. The method of claim 34, wherein the battery powers an electrotherapy device.

40. A method for dynamically controlling the load on a battery, comprising the steps of:

measuring at least one condition related to battery capacity; and

adjusting a power load on the battery based upon the at least one condition, wherein the at least one condition includes a slope of a capacity curve of the battery.

41. The method of claim 40, further comprising the step of indicating a low battery condition if battery voltage falls below a battery voltage threshold and the power load falls below a power threshold.

42. The method of claim 40, further comprising the step of indicating a replace battery condition if battery voltage falls below a battery voltage threshold and the power load falls below a minimum power threshold.

43. The method of claim 40, wherein the adjusting step comprises the step of adjusting the power load to optimize power delivery from the battery.

44. The method of claim 40, wherein the capacity curve is the product of battery voltage and the power load on the battery as a function of the power load.

45. The method of claim 43, further comprising the step of indicating a low battery condition if the optimum power falls below a power threshold.

46. The method of claim 43, further comprising the step of indicating a replace battery condition if the optimum power falls below a minimum power threshold.

47. The method of claim 40, wherein the battery powers an electrotherapy device.

48. In a battery system having a battery that includes a main stack for powering a main load and a sense cell for powering the main load and a dummy load, a method for dynamically controlling the load on the battery comprising the steps of:

measuring at least one condition of the battery; and

disabling the dummy load based upon the at least one condition of the battery.

49. The method of claim 48, further comprising the step of optimizing power delivery to the main load at an optimum power.

50. The method of claim 49, wherein the at least one condition is the optimum power falling below a power threshold.

51. The method of claim 49, wherein the optimizing step optimizes power based upon a slope of a capacity curve of the battery.

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52. The method of claim 51, wherein the capacity curve is the product of battery voltage and the power delivered to the main load as a function of the power delivered to the main load.

53. The method of claim 48, wherein the at least one condition is the battery voltage falling below a battery voltage threshold and power delivery to the main load falling below a power threshold.

54. The method of claim 48, wherein the at least one condition is the sense cell voltage falling below a sense cell voltage threshold and power delivery to the main load falling below a power threshold.

55. The method of claim 49, further comprising the step of indicating a low battery condition if the optimum power falls below a power threshold.

56. The method of claim 49, further the step of indicating a replace battery condition if the optimum power falls below a minimum power threshold.

57. The method of claim 48, further comprising the step of indicating a low battery condition if the battery voltage falls below a battery voltage threshold and power delivery to the main load falls below a power threshold.

58. The method of claim 48, further comprising the step of indicating a low battery condition if the sense cell voltage falls below a sense cell voltage threshold and power delivery to the main load falls below a power threshold.

59. The method of claim 48, further comprising the step of indicating a replace battery condition if battery voltage falls below a battery voltage threshold and power delivery to the main load falls below a minimum power threshold.

60. The method of claim 48, further comprising the step of indicating a replace battery condition if sense cell voltage falls below a sense cell voltage threshold and power delivery to the main load falls below a minimum power threshold.

61. The method of claim 48, wherein the battery powers an electrotherapy device.

62. In a battery system having a battery that includes a main stack for powering a main load and a sense cell for powering the main load and a dummy load, a method for dynamically controlling the load on the battery comprising the steps of:

optimizing power delivery to the main load at an optimum power level by measuring characteristics of the sense cell; and

optimizing power delivery to the main load by measuring characteristics of the main stack if the sense cell reaches a low capacity condition.

63. The method of claim 62, wherein the low capacity condition comprises the sense cell voltage falling below a sense cell voltage threshold and power delivery to the main load falling below a power threshold.

64. The method of claim 62, wherein the low capacity condition comprises the optimum power level falling below a power threshold.

65. The method of claim 62, wherein the optimizing step includes the step of adjusting power delivery based in part upon a slope of a capacity curve of the battery.

66. The method of claim 62, wherein the battery powers an electrotherapy device.

67. A method of providing a battery capacity indication in an electrotherapy device powered by a battery, the method comprising the following steps:

operating the electrotherapy device to treat a patient;

monitoring a battery parameter during the operating step;

providing a low battery capacity indication based on a value of the battery parameter, the providing step being

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performed while the electrotherapy device can provide at least three therapeutic electrical shocks to the patient before the battery is depleted.

68. The method of claim 67 wherein the providing step comprises providing a low battery capacity indication to a user.

69. The method of claim 67 wherein the providing step comprises providing a low battery indication based on the value of the battery parameter, the providing step being performed while the electrotherapy device can provide at least six electrical shocks to the patient before the battery is depleted.

70. The method of claim 67 wherein the providing step comprises providing a low battery indication based on the value of the battery parameter, the providing step being performed while the electrotherapy device can provide at least nine electrical shocks to the patient before the battery is depleted.

71. The method of claim 67 wherein the operating step comprises delivering a shock to a patient.

72. The method of claim 71 wherein the operating step further comprises monitoring the patient's ECG.

73. The method of claim 67 wherein the battery parameter comprises battery capacity curve slope.

74. The method of claim 67 wherein the providing step comprises providing a low battery capacity indication based on the value of the battery parameter, the providing step being performed while the electrotherapy device can provide at least three therapeutic electrical shocks to the patient before the battery is depleted, the shocks each being generated in 60 seconds or less.

75. The method of claim 67 wherein the providing step comprises providing a low battery capacity indication based on the value of the battery parameter, the providing step being performed while the electrotherapy device can provide at least three therapeutic electrical shocks to the patient before the battery is depleted, the shocks each being generated in 60 seconds or less.

76. The method of claim 67 wherein the electrotherapy device is an external defibrillator.

77. A method of providing a battery capacity indication in an electrotherapy device powered by a battery, the method comprising the following steps:

monitoring a battery parameter of the electrotherapy device battery;

providing a low battery capacity indication based on a value of the battery parameter, the providing step being performed while the electrotherapy device can provide at least three therapeutic electrical shocks to a patient before the battery is depleted.

78. The method of claim 77 wherein the providing step is performed while the electrotherapy device can provide at least six therapeutic electrical shocks to a patient before the battery is depleted.

79. The method of claim 77 wherein the providing step is performed while the electrotherapy device can provide at

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least nine therapeutic electrical shocks to a patient before the battery is depleted.

80. An apparatus for providing a battery capacity indication in an electrotherapy device powered by a battery, the apparatus comprising:

monitoring circuitry for monitoring a battery parameter of the electrotherapy device battery; and

indication circuitry for providing a low battery capacity indication based on a value of the battery parameter while the electrotherapy device can provide at least three therapeutic electrical shocks to a patient before the battery is depleted.

81. The apparatus of claim 80, the indication circuitry for providing a low battery capacity indication based on a value of the battery parameter while the electrotherapy device can provide at least six therapeutic electrical shocks to a patient before the battery is depleted.

82. The apparatus of claim 80, the indication circuitry for providing the low battery capacity indication based on a value of the battery parameter while the electrotherapy device can provide at least nine therapeutic electrical shocks to a patient before the battery is depleted.

83. The apparatus of claim 80, further comprising circuitry for treating a patient.

84. The apparatus of claim 81, further comprising circuitry for treating a patient.

85. The apparatus of claim 82, further comprising circuitry for treating a patient.

86. The apparatus of claim 80, wherein the indication circuitry provides a low battery capacity indication to a user.

87. The apparatus of claim 83, wherein the circuitry for treating a patient comprises circuitry for delivering a shock to the patient.

88. The apparatus of claim 87, wherein the circuitry for treating a patient comprises circuitry for monitoring the patient's ECG.

89. The apparatus of claim 80, wherein the battery parameter comprises battery capacity curve slope.

90. The apparatus of claim 80, wherein the circuitry for providing the low battery indication provides the low battery capacity indication based on the value of the battery parameter while the electrotherapy device can provide at least three electrical shocks to the patient before the battery is depleted, the shocks each being generated in 60 seconds or less.

91. The apparatus of claim 80, wherein the circuitry for providing the low battery indication provides the low battery capacity indication based on the value of the battery parameter while the electrotherapy device can provide at least three electrical shocks to the patient before the battery is depleted, the shocks each being generated in 30 seconds or less.

92. The apparatus of claim 80, wherein the electrotherapy device is an external defibrillator.

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US005899926A

United States Patent [19][11] **Patent Number:** **5,899,926****Ochs et al.**[45] **Date of Patent:** **May 4, 1999**

[54] **ENVIRONMENT-RESPONSIVE METHOD FOR MAINTAINING AN ELECTRONIC DEVICE SUCH AS AN EXTERNAL DEFIBRILLATOR**

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[21] **Appl. No.:** 09/120,680

[22] **Filed:** Jul. 21, 1998

Related U.S. Application Data

[63] Continuation of application No. 08/912,034, Aug. 15, 1997, Pat. No. 5,868,792.

[51] **Int. Cl.⁶** A61N 1/39

[52] **U.S. Cl.** 607/5; 702/63

[58] **Field of Search** 607/1, 2, 4, 5, 607/6, 9, 27, 29; 702/63

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Primary Examiner—William E. Kamm

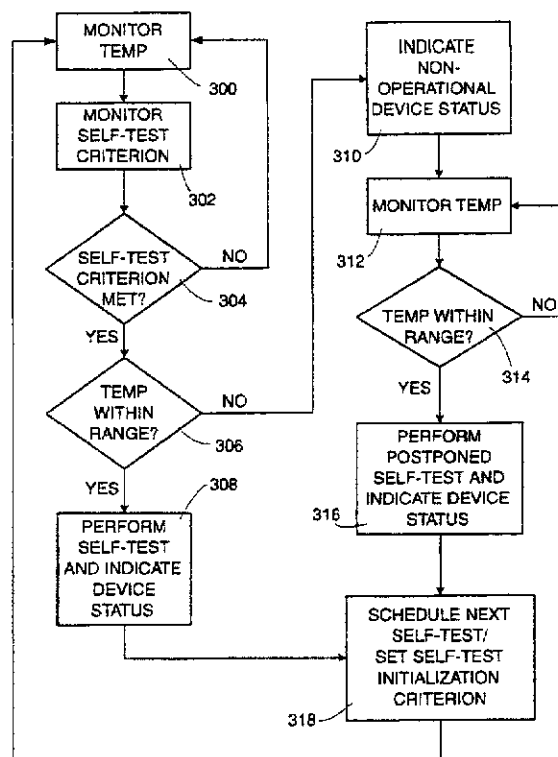
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[57] ABSTRACT

A method of maintaining an electronic device, the method including the steps of monitoring ambient an environmental condition such as temperature or humidity; monitoring a self-test initialization criterion; performing an automatic device self-test if the self-test criterion is met and if the environmental condition is within a predetermined range; and not performing the automatic device self-test if the self-test criterion is met but the environmental condition is outside the predetermined range. In a preferred embodiment, the device is an external defibrillator.

8 Claims, 4 Drawing Sheets



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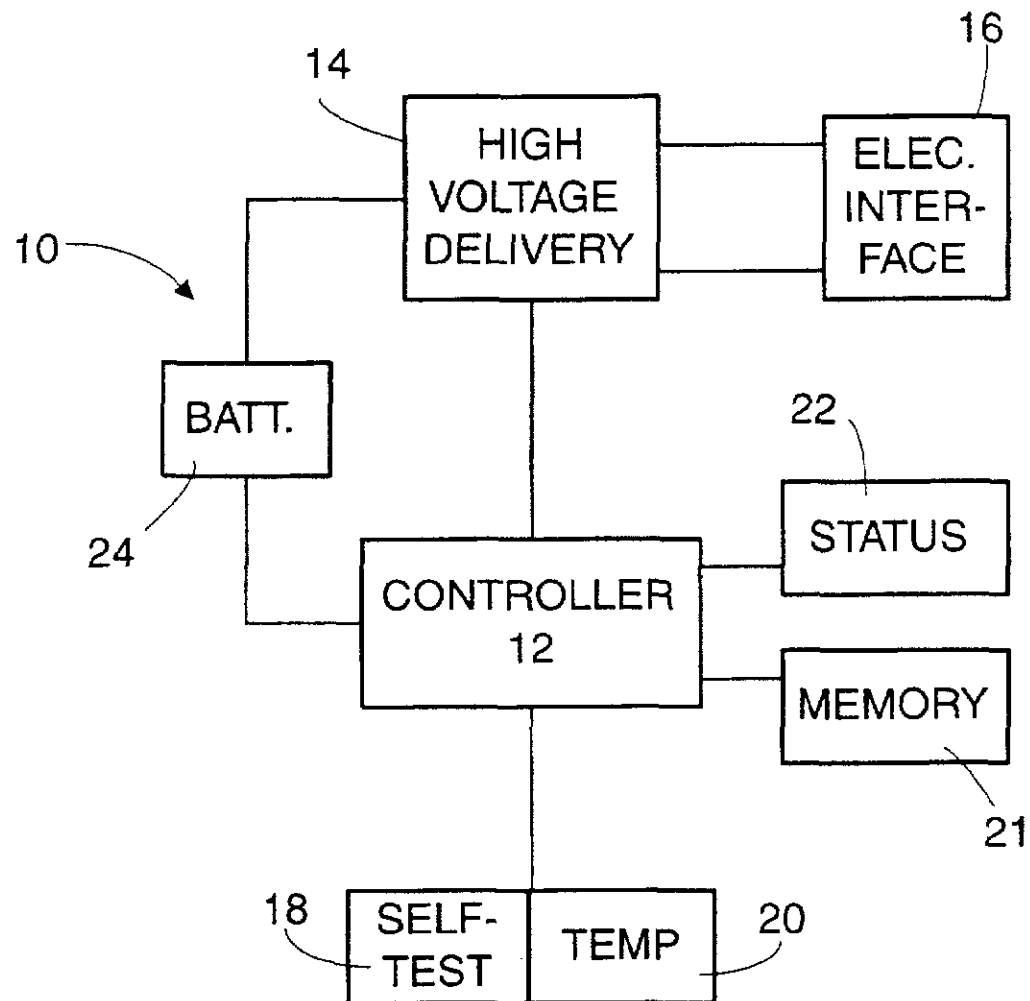


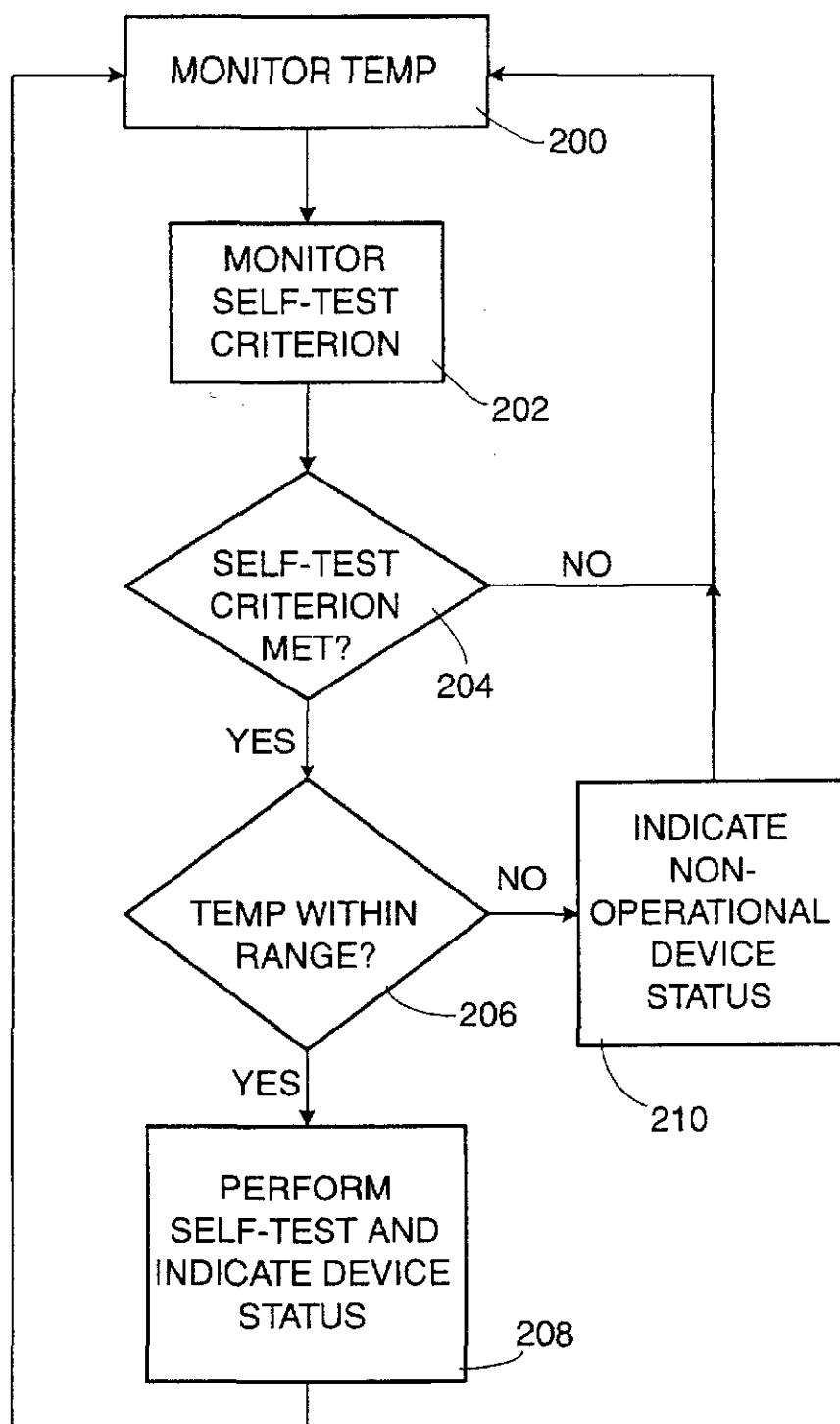
Fig. 1

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*Fig. 2*

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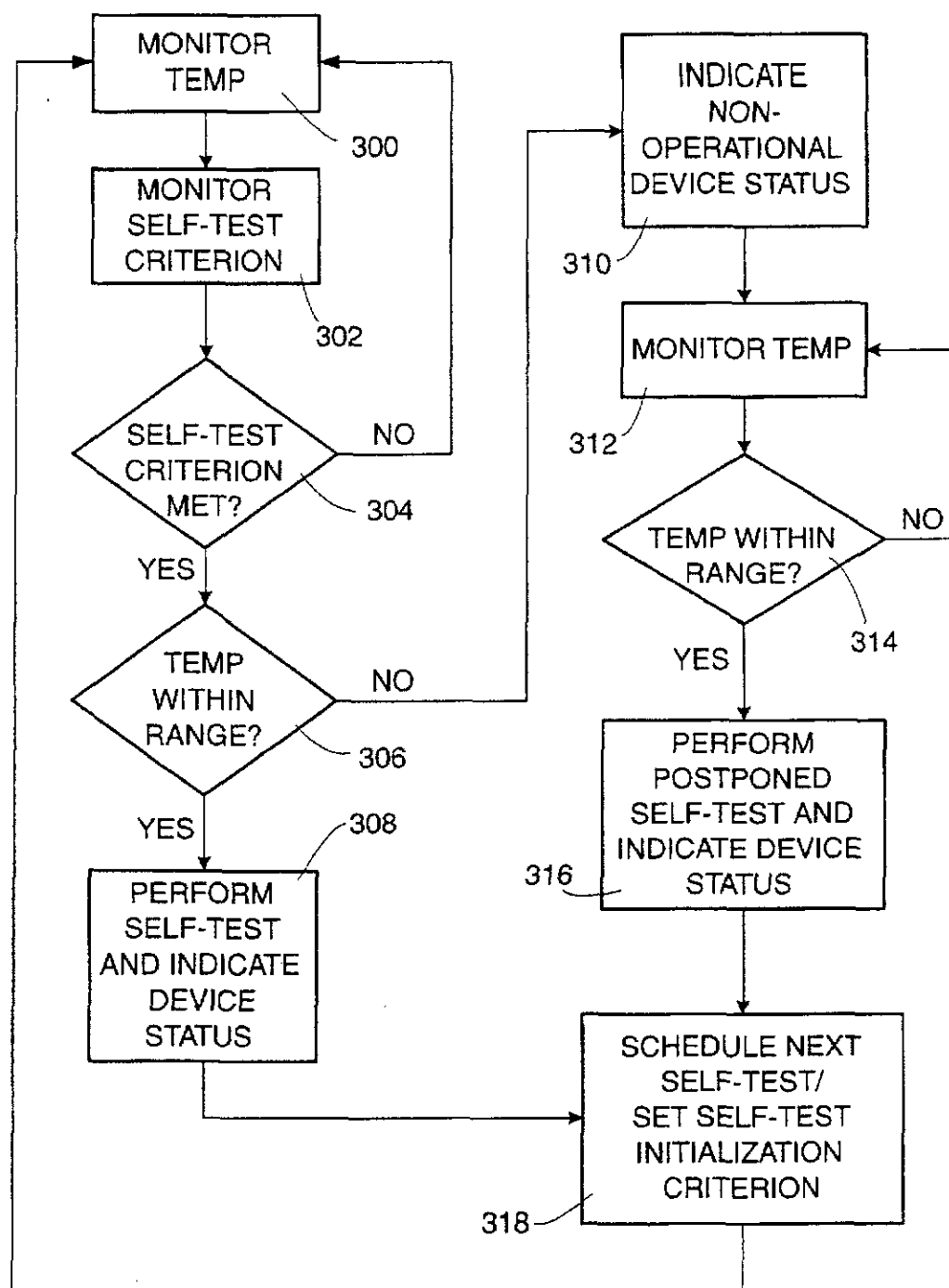


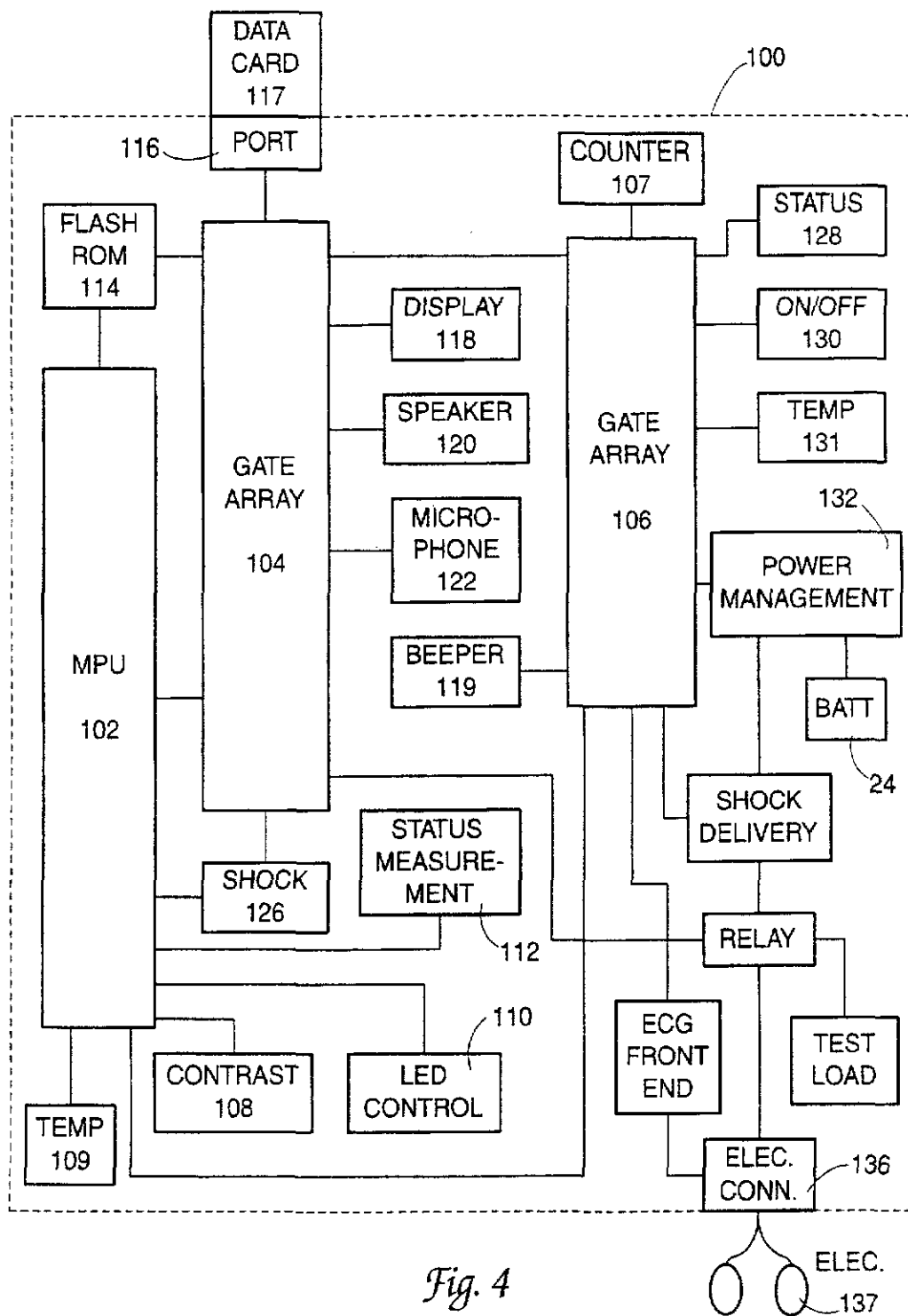
Fig. 3

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ENVIRONMENT-RESPONSIVE METHOD FOR MAINTAINING AN ELECTRONIC DEVICE SUCH AS AN EXTERNAL DEFIBRILLATOR

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation of application Ser. No. 08/912,034 filed on Aug. 8, 1997 now U.S. Pat. No. 5,868,792.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to electronic devices and environment-dependent methods of maintaining the devices and indicating operational status of the devices. In particular, this invention relates to temperature-dependent methods of maintaining external defibrillators and indicating their operational status.

2. Description of the Prior Art

Electronic devices that are infrequently used may be designed to perform automatic self-tests on a preset schedule, in response to an event or condition, or otherwise and to indicate the results of those self-tests to a potential user. An example can be found in certain external defibrillators that automatically self-test battery capacity and other defibrillator functions and components and indicate the results of those self-tests (i.e., the device's operational status) through visual displays and/or audible tones.

U.S. patent application Ser. No. 08/240,272 describes a battery-operated automatic external defibrillator (AED) designed for infrequent use. The device described in that patent application performs a variety of daily, weekly and monthly self-tests while in stand-by mode (i.e., when not powered-on to treat a patient, to review past treatment events, etc.) and indicates the operational status of the device using an "OK" or "Not OK" fail-safe display and through an audible tone generator. One of the device parameters monitored during the self-tests is remaining battery capacity.

The '272 application also suggests performing a group of self-tests automatically in response to exposure of the defibrillator to temperature extremes, although the exact nature of the environmentally-triggered self-tests is not disclosed.

The disclosure of the '272 application is incorporated herein by reference.

SUMMARY OF THE INVENTION

Environmental conditions can materially affect the manner in which an electronic device operates. In particular, a device self-test performed outside of a given environmental condition range could be inaccurate. It is therefore an object of this invention to take environmental measurements such as ambient temperature into account when operating an electronic device to perform an automatic self-test and when indicating operational status of the device.

This invention is a method of maintaining an electronic device, the method including the steps of monitoring an external environmental condition such as temperature or humidity; monitoring a self-test initialization criterion; performing an automatic device self-test if the self-test initialization criterion is met and if the environmental condition is within a predetermined range; and not performing the automatic device self-test if the self-test initialization criterion is

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met but the environmental condition is outside the predetermined range.

In certain embodiments, the method of this invention further includes, after the not performing step, performing the automatic device self-test when the environmental condition returns to the predetermined range after being outside the predetermined range. The method may also include the step of scheduling an additional automatic device self-test after the environmental condition returns to the predetermined range after being outside the predetermined range.

In other embodiments, the method includes, before the performing step, the step of waking the device from a stand-by mode. The method may also include the step of changing an indication of device operating status if the scheduled automatic device self-test is not performed.

In yet other embodiments, the method of this invention includes the step of changing an indication of device operating status if the environmental condition is outside of the predetermined range.

In the preferred embodiment of this invention, the electronic device is an external defibrillator.

The invention is described in more detail below with reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows the major components of an automatically self-testing external defibrillator.

FIG. 2 is a flow chart showing one aspect of this invention.

FIG. 3 is a flow chart showing another aspect of this invention.

FIG. 4 is a schematic drawing of an external defibrillator according to a preferred embodiment of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

This invention may be used in electronic devices that perform one or more automatic self-tests when one or more self-test initialization criteria (such as the passage of time) are met. The invention is particularly useful in battery-operated devices, since operation outside of a prescribed temperature range may be detrimental to battery capacity. While the preferred embodiment of the invention is explained below with respect to an automatically self-testing battery-operated external defibrillator, it should be understood that the invention may be used in other contexts as well.

There are at least two reasons why an electronic device should not be operated outside of a specified temperature range. First, operation outside of the specified temperature range may harm certain temperature-sensitive components of the device. Second, if the device is battery-operated, an attempt to operate the device outside of a specified temperature range may render the battery inoperable or inordinately reduce the battery's capacity.

In FIG. 1, external defibrillator 10 includes a high voltage delivery system 14 operating under the control of controller 12 to deliver an electric shock to an electrode interface 16. The high voltage delivery system may include a power transformer, switches and other circuit elements known in the defibrillator art. Power for operating the defibrillator and for the electrical shock comes from battery 24.

In the preferred embodiment, defibrillator 10 automatically performs self-tests under the control of a self-test

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system 18 and indicates its operational status on a status indicator 22. The self-tests may include a battery capacity test and tests of other defibrillator systems or components. Status indicator 22 may be any object which informs the user of device status through visual, audible, tactile, or other sensory means (e.g., a light, a text display, an electrically or mechanically altered symbol, a beeper, or a spoken word generator). The self-test system may be an integral part of the controller 12, of course, without departing from the scope of this invention.

Details of a defibrillator self-test system (including a battery capacity test) may be found in U.S. patent application Ser. No. 08/240,272, the disclosure of which is incorporated herein by reference. Details of a preferred battery capacity test may be found in U.S. Pat. No. 5,483,165, which is also incorporated herein by reference. The exact nature and design of the battery capacity test and other self-tests form no part of this invention.

Defibrillator 10 has a temperature sensor 20 which can be used to determine whether the ambient temperature is within the defibrillator's specified operating range. Controller 12 may also use temperature sensor 20 to identify warning states or other device operational status and to indicate device status on status indicator 22 in response to a change in temperature (whether or not the defibrillator is within its specified operating range).

External defibrillator 10 has at least three operational modes. In use mode, a controller 12 operates a high-voltage delivery system 14 to deliver an electrical shock to a patient through an electrode interface 16. In self-test mode, controller 12 automatically tests one or more of the defibrillator's circuits or functions (such as the defibrillator's battery) in response, e.g., to a request for a self-test from a self-test signal generator 18 and/or a temperature monitor 20 and indicates defibrillator operating status on a status indicator 22. More details about automatic self-tests in external defibrillators may be found in the '272 patent application. The exact nature of the self-tests is not a part of this invention, except as indicated herein.

Finally, in stand-by mode, controller 12 conserves power by simply monitoring temperature and other self-test criteria (such as elapsed or real time) and by watching for a request to use the defibrillator, in which cases the defibrillator will move out of stand-by mode to self-test mode or use mode, respectively. Power for the electric shock and for operating the defibrillator is supplied by a battery 24.

FIG. 2 is a flow chart showing one aspect of this invention. FIG. 2 shows a method of maintaining an electronic device, such as the external defibrillator of FIG. 1. This method presumes that the device automatically initiates a self-test according to one or more criteria (such as the passage of time) and indicates the result of the self-test (i.e., the device's operational status) on a status indicator. Because of the potential adverse affects of temperature on the operation of the device in self-test mode, the device monitors temperature in block 200 as well as at least one self-test initialization criterion, as in block 202. The device continues to monitor temperature and to watch for the self-test initialization criterion until the self-test initialization criterion is met.

If the self-test initialization criterion is met (block 204), the device determines at block 206 whether the monitored temperature is within a specified range. If so, the device performs its self-test and indicates the result of the self-test on a status indicator (block 208).

If, however, the monitored temperature is outside of the specified range when the self-test initialization criterion is

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met, the device does not perform the self-test. Instead, the device indicates a non-operational status on the status indicator (block 210) to show that the device's true status is uncertain due to its inability to perform a self-test. The device then continues to monitor temperature and watch for a self-test initialization criterion to be satisfied. In this instance, the self-test initialization criterion may simply be a return of the monitored temperature to the specified range, in which case the device would proceed to perform its postponed self-test and indicate the result of the test on its status indicator (block 208). In other words, the self-test initialization criterion need not be constant. It may change in response to, e.g., the device's inability to perform an earlier self-test due to an out-of-range temperature.

FIG. 3 is a flow chart showing another aspect of this invention's method of maintaining an electronic device such as an external defibrillator. In this embodiment, the device monitors temperature and a self-test initialization criterion (blocks 300-302), as in the FIG. 2 embodiment. If the self-test initialization criterion is met and the monitored temperature is within a specified range, the device performs its automatic self-test and indicates device status as a result of that test on a device status indicator (blocks 304-308). The device then sets a self-test initialization criterion that will trigger a device self-test, such as by scheduling the next self-test (i.e., the initialization criterion is the passage of time) (block 318).

If, however, the self-test initialization criterion is met but the monitored temperature is not within the specified temperature range, the device indicates a non-operational or warning status on the device's status indicator (block 310) without performing a self-test. The device continues to monitor temperature (block 312), and if the monitored temperature enters a specified temperature range (which may be the same temperature range specified in block 306), the device performs the postponed self-test and indicates device status as a result of that test on a device status indicator (block 316). The device then sets a self-test initialization criterion that will trigger a device self-test, such as by scheduling the next self-test (i.e., the criterion is the passage of time) (block 318).

In a preferred embodiment, the self-test initialization criterion set in block 318 differs depending on whether the device has just performed a self-test that was postponed due to out-of-range temperatures or a regularly-scheduled self-test. For example, if the device normally performs an automatic self-test every 24 hours, and if the device has just performed a self-test that had been postponed beyond its scheduled time due to the monitored temperature being out of the specified range, the device may schedule the next automatic self-test to occur in 8 hours instead of 24 hours in order to move the daily self-test to a time more suitable to the performance of the self-test.

FIG. 4 is a schematic drawing of an external defibrillator according to a preferred embodiment of this invention. Many of the elements shown in FIG. 4 bear no relation to this invention. They have been included solely to show one context in which the invention may operate.

In the external defibrillator 100 shown in FIG. 4, functions of the controller of FIG. 3 are divided among an MPU 102 and two gate arrays, 104 and 106. Gate array 106 also performs the functions of the self-test signal generator of FIG. 3. Because it was designed for infrequent use, defibrillator 100 is usually in stand-by mode. Gate array 106 monitors temperature every 2 seconds in stand-by mode via a temperature sensor 131 while the MPU and other parts of the device are inactive.

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While in stand-by mode, gate array 106 watches for a wake-up condition, such as when self-test counter 107 counts down to "1" or if temperature sensor 131 indicates that a predetermined temperature has been reached. The actual self-test criteria are not part of this invention. When a wake-up condition has been reached, gate array 106 causes MPU 102 to wake-up, and MPU 102 determines the reason it was awakened by reading an ONOFF_REASON register within gate array 106. MPU 102 then takes steps (i.e., executes code) appropriate to the reason it was awakened.

For example, in a preferred embodiment, external defibrillator 100 automatically performs groups of self-tests daily, weekly (every 7th day, instead of the daily self-test group) and monthly (every 28th day, instead of the daily and weekly self-test groups). At the conclusion of the test, counter 107 is set at a number (43,200) that will count to "1" in approximately 24 hours at 2 second decrements. When counter 107 reaches "1", gate array 106 sets its ONOFF_REASON register to "self-test" and awakens MPU 102 (i.e., leaves stand-by mode). MPU 102 then looks to the ONOFF_REASON register, determines that it was awakened to perform a self-test, looks to Flash ROM 114 to determine where it is in the self-test sequence (i.e., whether a daily, weekly or monthly self-test group is to be performed next), and proceeds to execute the appropriate code to perform that test. The operational status of the defibrillator as determined by the self-test is indicated by status indicator 128 and, in the event of a non-operational status, possibly by beeper 119 as well.

If, however, the temperature is determined by A/D temperature sensor 109 to be outside of the specified temperature range (which, in the preferred embodiment, is 0-50 °C.), external defibrillator 100 aborts the scheduled automatic self-test, sets an internal TEST_POSTPONED warning, disables counter 107 (by setting it at "0") and indicates a non-operational status on status display 128. Defibrillator 100 then sets HI and LO target temperature registers within gate array 106 to be just within the specified temperature range and returns to stand-by mode. Every two seconds while in stand-by mode, gate array 106 compares the temperature indicated by temperature sensor 131 with the HI and LO temperature target registers. If the current temperature is higher than the HI register or lower than the LO register, gate array 106 awakens MPU 102 and sets the wake-up reason to Extreme Environmental Change.

The TEST_POSTPONED warning causes MPU 102 to execute the postponed automatic self-test after the temperature returns to the specified temperature range. In addition, at the end of the postponed self-test, instead of scheduling counter 107 to request another automatic self-test in 24 hours, MPU 102 schedules the next self-test to take place in 8 hours.

In the preferred embodiment, gate array temperature sensor 131 is a thermistor (such as model no. AL03006-535K-145-G1 from Keystone) and A/D temperature sensor 109 is an Analog Devices AD22100. Sensor 109 requires more power than sensor 131 and is therefore used only when the device is not in stand-by mode. While the A/D tempera-

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ture sensor 109 is sufficiently linear over the useful range of temperatures that might be encountered by the device, temperature sensor 131 is non-linear above 50° C. and below -10° C. A correction must be added to the sensor 131 temperature readings in the non-linear range to compensate for the non-linearity.

Modifications to the invention embodiments described above will be apparent to those skilled in the art. Such modifications are within the scope the invention.

What is claimed is:

1. A method of preventing adverse effects of an environmental condition on an electronic device comprising:

monitoring said environmental condition;

monitoring a self-test initialization criterion;

performing an automatic device self-test if said self-test initialization criterion is met and if said environmental condition is within a predetermined range of values; and

not performing said automatic device self-test if said self-test initialization criterion is met and if said environmental condition is outside said predetermined range of values.

2. A method of preventing adverse effects of an environmental condition on an electronic device according to claim 1 further comprising, after the not performing step, performing said automatic device self-test if said environmental condition returns to said predetermined range of values after being outside said predetermined range of values.

3. A method of preventing adverse effects of an environmental condition on an electronic device according to claim 2 further comprising scheduling an additional automatic device self-test after said environmental condition returns to said predetermined range of values after being outside said predetermined range of values.

4. A method of preventing adverse effects of an environmental condition on an electronic device according to claim 1 further comprising, before the performing step, waking up said electronic device from a stand-by mode.

5. A method of preventing adverse effects of an environmental condition on an electronic device according to claim 1 further comprising providing an indication of device operating status.

6. A method of preventing adverse effects of an environmental condition on an electronic device according to claim 5 further comprising changing said indication of device operating status if said automatic self-test is not performed.

7. A method of preventing adverse effects of an environmental condition on an electronic device according to claim 5 further comprising changing said indication of device operating status if said environmental condition is outside said predetermined range of values.

8. A method of preventing adverse effects of an environmental condition on an electronic device according to claim 1 wherein said environmental condition comprises temperature.

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US005904707A

United States Patent [19]
Ochs et al.

[11] **Patent Number:** **5,904,707**
 [45] **Date of Patent:** **May 18, 1999**

[54] **ENVIRONMENT-RESPONSE METHOD FOR
 MAINTAINING AN EXTERNAL MEDICAL
 DEVICE**

[75] **Inventors:** **Dennis E. Ochs, Bellevue; Ian G.
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[73] **Assignee:** **HeartStream, Inc., Seattle, Wash.**

[21] **Appl. No.:** **08/911,710**

[22] **Filed:** **Aug. 15, 1997**

[51] **Int. Cl.⁶** **A61N 1/39**

[52] **U.S. Cl.** **607/6; 607/63**

[58] **Field of Search** **607/4, 5, 6, 9,
 607/17-18, 21, 27, 29, 63, 64, 1, 2, 10**

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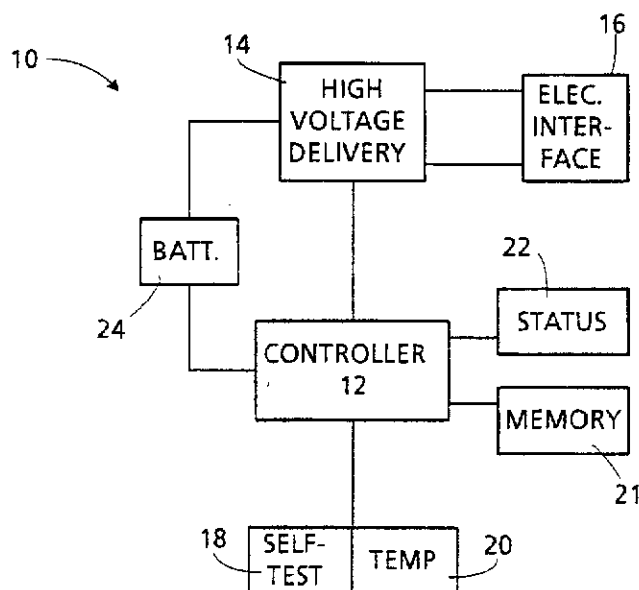
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Primary Examiner—William E. Kamm
Assistant Examiner—George R. Evanisko
Attorney, Agent, or Firm—Cecily Anne Snyder

[57] **ABSTRACT**

A method of indicating operational status of an electronic device, the device providing an indication of device operational status as a result of a self-test, the method including the following steps: monitoring an environmental condition; changing an indication of device operational status from a first indication to a second indication if the monitored environmental condition changes from a first condition to a second condition, this changing step being performed without performing a self-test. In certain embodiments, the monitored environmental condition is a monitored temperature, the first condition is a first temperature and the second condition is a second temperature. The electronic device may be battery-operated, in which case the self-test is a battery capacity test. In these embodiments, the method also may include the step of performing the battery capacity test when the monitored temperature reaches the second temperature if there is no indication of device operational status corresponding to the second temperature stored in memory, the second temperature is lower than a temperature associated with an indication of a non-warning device operational status stored in memory, and the second temperature is higher than a temperature associated with an indication of a warning operational status; and indicating device operational status as a result of the battery capacity test. The method may also include the step of storing in memory an association between the second temperature and device operational status.

20 Claims, 5 Drawing Sheets



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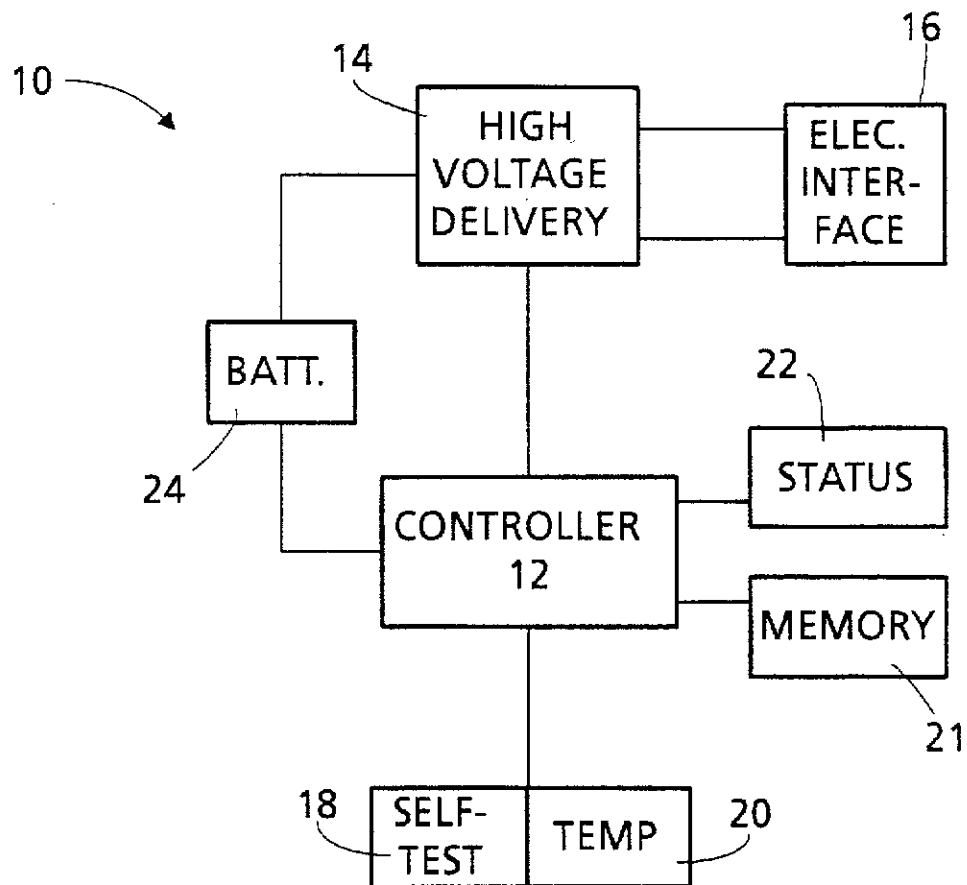


Fig. 1

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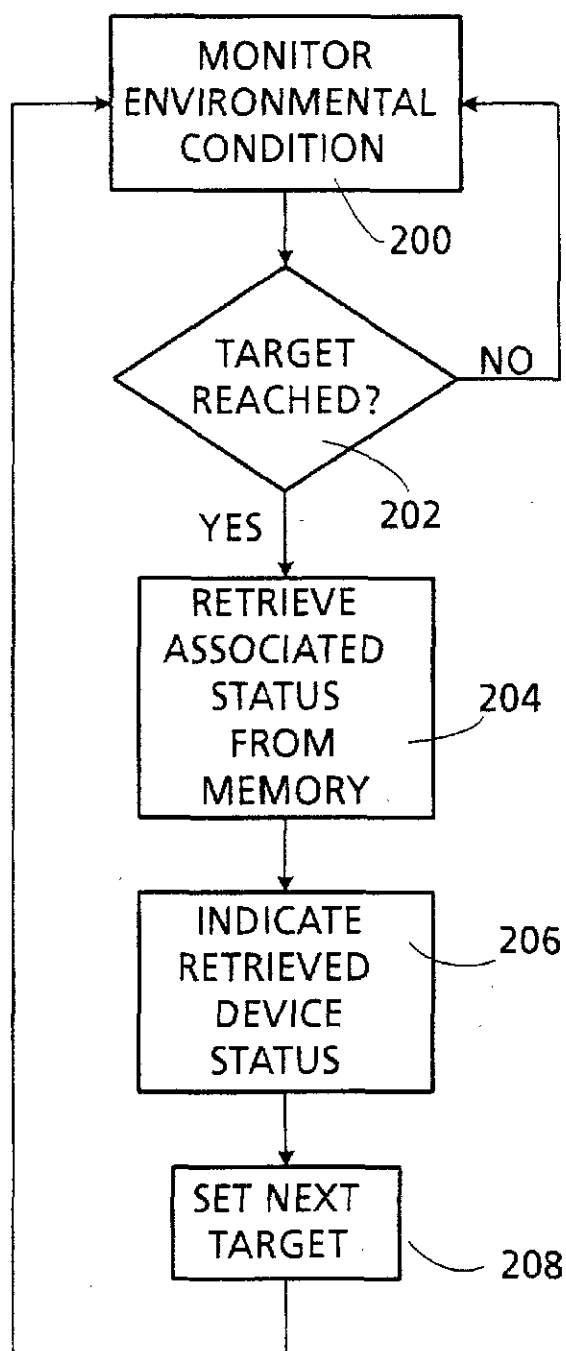


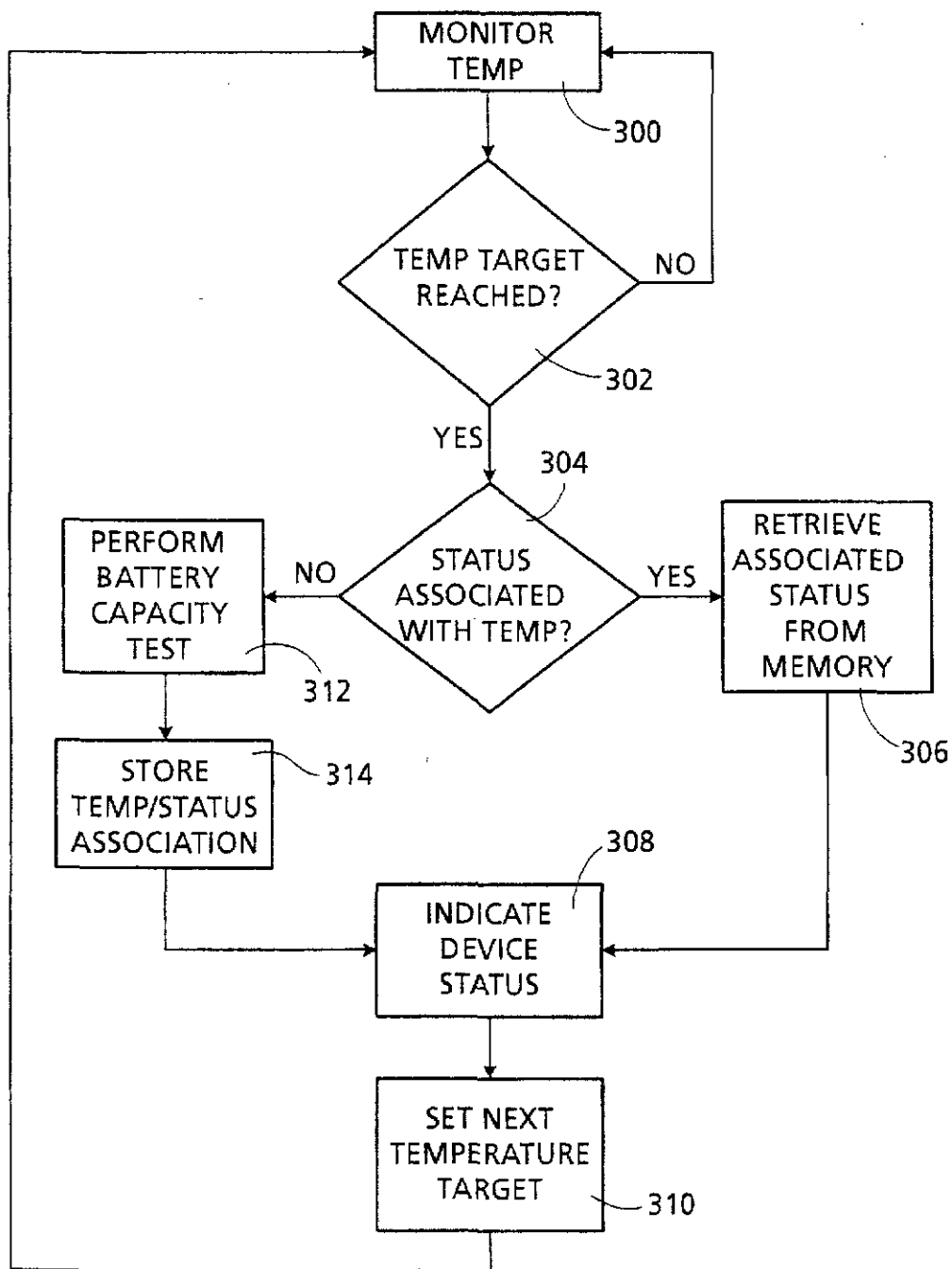
Fig. 2

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*Fig. 3*

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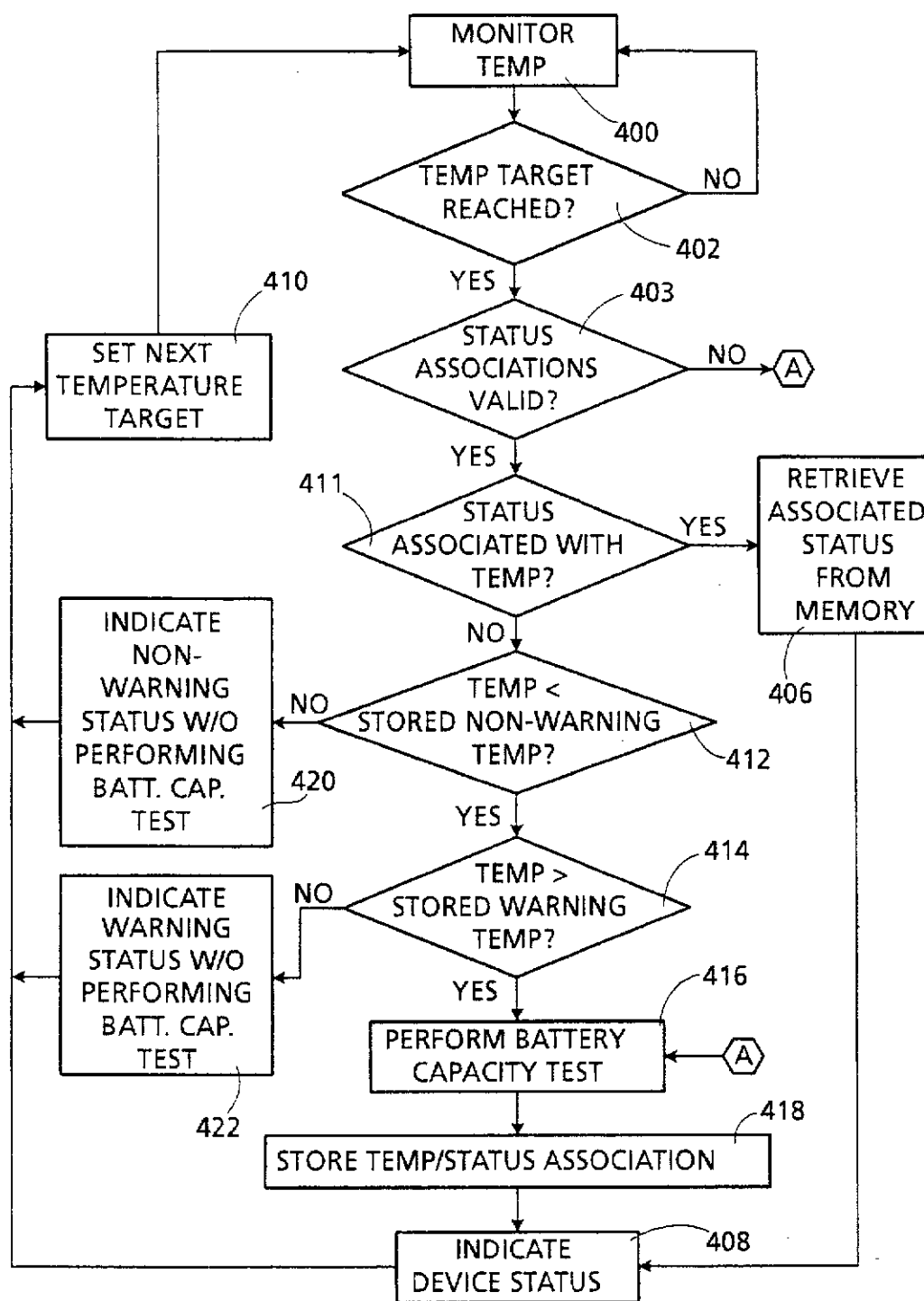


Fig. 4

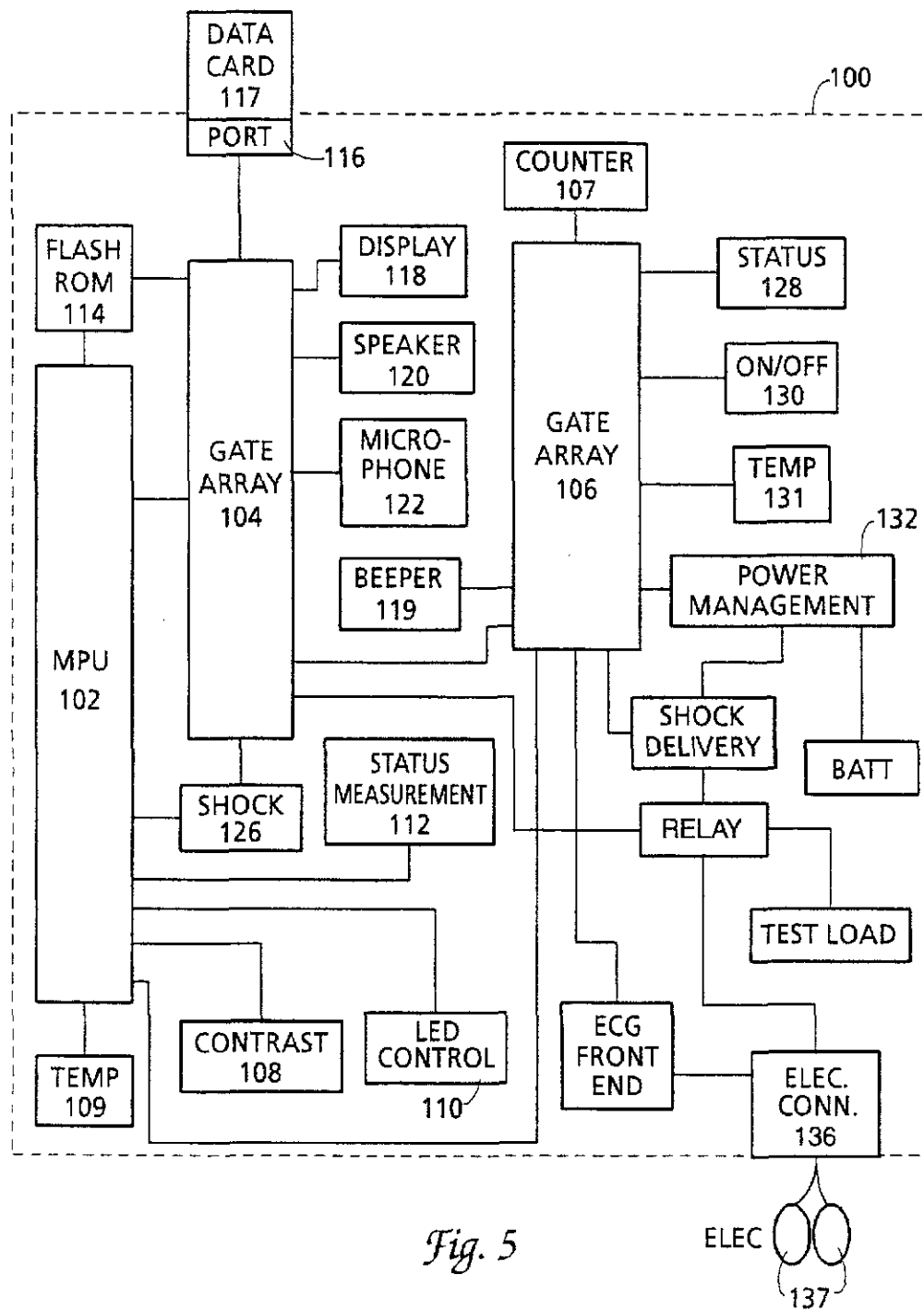


Fig. 5

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ENVIRONMENT-RESPONSE METHOD FOR MAINTAINING AN EXTERNAL MEDICAL DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to electronic devices and environment-dependent methods of maintaining the devices and indicating operational status of the devices. In particular, this invention relates to temperature-dependent methods of maintaining battery-operated external defibrillators and indicating their operational status.

2. Description of the Prior Art

Electronic devices that are infrequently used may be designed to perform automatic self-tests on a preset schedule, in response to an event or condition, or otherwise and to indicate the results of those self-tests to a potential user. An example can be found in certain external defibrillators that automatically self-test battery capacity and other defibrillator functions and components and indicate the results of those self-tests (i.e., the device's operational status) through visual displays and/or audible tones.

U.S. patent application Ser. No. 08/240,272 describes a battery-operated automatic external defibrillator (AED) designed for infrequent use. The device described in that patent application performs a variety of daily, weekly and monthly self-tests while in stand-by mode (i.e., when not powered-on to treat a patient, to review past treatment events, etc.) and indicates the operational status of the device using an "OK" or "Not OK" fail-safe visual display and using an audible tone generator. One of the device parameters monitored during the self-tests is remaining battery capacity.

The '272 application also suggests performing a group of self-tests automatically in response to exposure of the defibrillator to temperature extremes, although the exact nature of the environmentally-triggered self-tests is not disclosed. The disclosure of the '272 application is incorporated herein by reference.

There are many other types of battery-operated devices as well. Some battery-operated devices automatically track remaining battery capacity and indicate device status or make some other change based, at least in part, on remaining battery capacity. See, e.g., U.S. Pat. No. 3,895,284; U.S. Pat. No. 4,207,514; U.S. Pat. No. 4,525,055; U.S. Pat. No. 4,693,119; U.S. Pat. No. 4,725,784; U.S. Pat. No. 4,931,737; U.S. Pat. No. 5,065,084; U.S. Pat. No. 5,130,659; U.S. Pat. No. 5,162,741; and U.S. Pat. No. 5,483,165. The disclosures of these patents are incorporated herein by reference.

For example, Bates U.S. Pat. No. 5,162,741 describes a battery monitor that continuously samples the battery load current and temperature. The device continuously displays remaining battery capacity based on a temperature-compensated measurement of the amount of current drawn from the battery.

Hishiki U.S. Pat. No. 4,931,737 describes a battery capacity measurement circuit using a capacitor having thermal and age-variation characteristics to compensate for the thermal and age-variation characteristics of the battery. Specifically, the capacitor's capacitance, like the battery capacity, is maximum at room temperature and decreases with either an increase or decrease in ambient temperature. The capacitor is used to generate a pulse signal whose frequency varies with temperature as the capacitance (and therefore the battery capacity) changes, with the frequency

being lowest at room temperature and increasing with an increase or decrease in ambient temperature. The pulse signals are counted by a counter to compute battery discharge and, thereby, remaining battery capacity.

Landau et al. U.S. Pat. No. 5,454,710 describes a battery monitoring and display system which adjusts actual measurements of remaining battery capacity by fixed percentages when the ambient temperature is in certain defined ranges.

SUMMARY OF THE INVENTION

An indication of device operating status can be critically important for certain electronic devices. For example, external defibrillators are used to treat victims of sudden cardiac arrest through the delivery of an electric shock. Time is of the essence in getting this defibrillation therapy to the victim. In fact, the patient's chances of survival are reduced by about 10% for each minute that therapy is withheld. If a defibrillator incorrectly reports its operational status, valuable time can be lost in determining the cause of the error and remedying the problem. A defibrillator's operational status indicator must therefore be extremely reliable in its indication of device status.

Environmental conditions can materially affect the operational status of an electronic device (such as a defibrillator). In particular, high and, especially, low temperatures can have a dramatic effect on available battery capacity. It is therefore an object of this invention to take ambient environmental conditions into account when indicating operational status of an electronic device, making that status indication more responsive to environmental changes, and thereby improving the reliability of that status indication.

Self-testing itself can materially affect the operational status of an electronic device by, for instance, depleting resources such as battery power. It is therefore another object of this invention to change, under certain environmental conditions, the indication of device operational status based on historical self-test results without actually performing a new self-test.

The invention is a method of indicating operational status of an electronic device (such as an external defibrillator), the device providing an indication of device operational status as a result of a self-test, the method including the following steps: monitoring an environmental condition (such as temperature); changing an indication of device operational status from a first indication to a second indication if the monitored environmental condition changes from a first condition to a second condition, this changing step being performed without performing a self-test. The first indication may be a non-warning indication and the second indication may be a warning indication. In one embodiment, the second condition is a target condition, and the method further includes the step of setting a new target condition.

In certain embodiments, the monitored environmental condition is a monitored temperature, the first condition is a first temperature and the second condition is a second temperature. The electronic device may be battery-operated, in which case the self-test is a battery capacity test. In these embodiments, the method also may include the step of performing the battery capacity test when the monitored temperature reaches the second temperature if there is no indication of device operational status corresponding to the second temperature stored in memory, the second temperature is lower than a temperature associated with an indication of a non-warning device operational status stored in memory, and the second temperature is higher than a tem-

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perature associated with an indication of a warning operational status; and indicating device operational status as a result of the battery capacity test. The method may also include the step of storing in memory an association between the second temperature and device operational status.

In other embodiments, the method includes, without performing a self-test, the step of changing the indication of device operational status from the second indication to the first indication if the monitored environmental condition reaches the first condition. The method may also include the step of retrieving from memory the second indication of device operational status, the second indication of device operational status being associated with the second condition. In such case, the method may include, following the retrieving step but prior to the changing step, the step of determining whether the second indication of device operational status is valid, the changing step being performed only if the second indication of device operational status is valid. The method may also include the step of performing a self-test if the second indication of device operational status is invalid.

In still other embodiments, the method includes the steps of performing an automatic self-test when the monitored environmental condition reaches the second condition if there is no indication of device operational status corresponding to the second condition stored in memory; and indicating device operational status as a result of the self-test. The method may also include storing in memory an association between the second condition and device operational status.

In another embodiment, the invention is a method of indicating operational status of a battery-operated, automatically self-testing device (such as an external defibrillator), the device providing an indication of device operational status as a result of a self-test, and includes the following steps: monitoring a temperature; if the monitored temperature reaches a target temperature, retrieving from memory associations between temperature and indications of device operational status; if the highest temperature associated with an indication of a warning device operational status is higher than the lowest temperature associated with an indication of a non-warning device operational status, performing an automatic battery capacity test and indicating device operational status as a result of the battery capacity test. In one embodiment, the method includes the step of storing in memory an association between the target temperature and an indication of device operational status.

In yet another embodiment, the invention is a method of indicating operational status of an electronic device (such as an external defibrillator), including the following steps: monitoring an environmental condition (such as temperature); performing a plurality of self-tests (such as battery capacity tests) at a plurality of environmental conditions to determine as self-test results whether device operational status is acceptable or unacceptable at each environmental condition; storing an association of self-test results and environmental conditions at which the self-tests were performed; and indicating operational status of the electronic device based on the self-test results. In one embodiment, the method includes the step of storing a maximum number of self-test results.

In one particular embodiment the environmental condition is temperature and the self-test is a battery-capacity test, and the method includes the following steps: if a battery capacity test has not been performed at a target temperature,

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and if the target temperature is lower than the temperature of the lowest acceptable battery capacity test result and higher than the temperature of the highest unacceptable battery capacity test result: performing a battery capacity test;

storing an association of a battery capacity test result from the previous step and the target temperature; indicating the battery capacity test result stored in the previous step; and setting a new target temperature.

The method may also include, if a temperature of an unacceptable battery capacity test result is higher than a temperature of an acceptable battery capacity test result, the steps of:

performing a battery capacity test; storing an association of a battery capacity test result from the previous step and temperature; and indicating the battery capacity test result stored in the previous step. In this embodiment, the method may also include, if the device battery capacity has been tested at the target temperature, the step of indicating the stored battery capacity test result associated with the target temperature.

The invention will be described in more detail below with reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an example of a defibrillator which can be used to implement the methods of this invention.

FIG. 2 is a flowchart showing one preferred method of indicating the operational status of a battery-operated, automatically self-testing device.

FIG. 3 is a flowchart showing another embodiment of the methods of this invention.

FIG. 4 is a flowchart showing yet another embodiment of this invention.

FIG. 5 is a block diagram showing an external defibrillator that may be used to implement the methods of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As discussed above, environmental changes can affect the results of a battery self-test and potentially other self-tests as well. It is not always necessary, and sometimes undesirable, to run a self-test, however. One aspect of this invention, therefore, is a method of indicating the operational status (e.g., through a "warning" indication) of an electronic, self-testing device based on recent historical self-test results, without actually performing a new self-test, such as a battery capacity test. This aspect of the invention is illustrated with reference to a the battery-operated external defibrillator shown in FIG. 1. It should be understood that this aspect of the invention is applicable to other battery-operated and non-battery-operated electronic devices as well.

In FIG. 1, external defibrillator 10 includes a high voltage delivery system 14 operating under the control of controller 12 to deliver an electric shock to an electrode interface 16. The high voltage delivery system may include a power transformer, switches and other circuit elements known in the defibrillator art. Power for operating the defibrillator and for the electrical shock comes from battery 24.

In the preferred embodiment, defibrillator 10 automatically performs self-tests under the control of a self-test system 18 and indicates its operational status on a status indicator 22. The self-tests may include a battery capacity test and tests of other defibrillator systems or components.

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Status indicator 22 may be any object which informs the user of device status through visual, audible, tactile, or other sensory means (e.g., a light, a text display, an electrically or mechanically altered symbol, a beeper, or a spoken word generator). The self-test system may be an integral part of the controller 12, of course, without departing from the scope of this invention.

Details of a defibrillator self-test system (including a battery capacity test) may be found in U.S. patent application Ser. No. 08/240,272, the disclosure of which is incorporated herein by reference. Details of a preferred battery capacity test may be found in U.S. Pat. No. 5,483,165, which is also incorporated herein by reference. The exact nature and design of the battery capacity test and other self-tests form no part of this invention.

Defibrillator 10 has an environmental sensor 20 which can be used to determine whether an environmental condition (such as temperature, humidity, chemical concentration, radiation level, altitude, mechanical shock or vibrations, etc.) is within the defibrillator's specified operating range and whether that environmental condition has exceeded some predefined limit. Controller 12 may also use sensor 20 to identify warning states or other device operational status and to indicate device status on status indicator 22 in response to a change in the environmental condition (whether or not the defibrillator is within its specified operating range) without performing a battery capacity test or other self-test.

External defibrillator 10 has at least three operational modes. In use mode, a controller 12 operates a high-voltage delivery system 14 to deliver an electrical shock to a patient through an electrode interface 16. In self-test mode, controller 12 automatically tests one or more of the defibrillator's circuits or functions (such as the defibrillator's battery) in response, for example, to a request for a self-test from a self-test initialization generator 18 and/or an environmental sensor 20 and indicates defibrillator operating status on a status indicator 22. More details about automatic self-tests in external defibrillators may be found in the '272 patent application. The exact nature of the self-tests is not a part of this invention, except as indicated herein.

Finally, in stand-by mode, controller 12 conserves power by simply monitoring temperature and other self-test initialization criteria (such as elapsed or real time) and by watching for a request to use the defibrillator, in which cases the defibrillator will move out of stand-by mode to self-test mode or use mode, respectively. Power for the electric shock and for operating the defibrillator is supplied by battery 24.

In one embodiment of the invention, defibrillator 10 stores in memory 21 associations between environmental conditions and device operational status indications. For example, warning indications may be stored in association with particular temperatures or temperature ranges, and non-warning indications may be stored in association with other temperatures or temperature ranges. In some cases, defibrillator 10 uses these stored associations between environmental conditions and device status indications to indicate warnings, or to remove warning indications, in response to environmental changes monitored by sensor 20 without actually performing new battery capacity tests or other self-tests.

One preferred method of indicating the operational status of an electronic, self-testing device is shown in the flowchart of FIG. 2. An environmental condition (such as temperature, humidity, etc.) is monitored (block 200) to determine whether a predetermined target has been reached (block

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202). If so, the device retrieves from memory any device operational status that may be stored in association with the target (block 204). At block 206, the device uses the stored status information to indicate device status on a device status indicator (such as status indicator 22 of the defibrillator shown in FIG. 1). At block 208, the device sets the next target that will trigger the retrieval of device status information from memory and continues to monitor the environmental condition. In this way, the device is able to indicate changes in device operational status based on historical self-test results without actually performing a new battery capacity test or other self-test.

FIG. 3 is a flowchart showing another embodiment of the invention. In this embodiment, the environmental condition is temperature, which is monitored (block 300) to determine whether a predetermined temperature target has been reached (block 302). If there is a device operational status stored in device memory in association with the target temperature, the associated device operational status is retrieved from memory (block 306) and indicated via the device status indicator (block 308). If, however, there is no device operational status information stored in association with the target temperature, the device performs a battery capacity test or other self-test (block 312), stores in device memory an indication of device status in association with the target temperature (block 314) and indicates the newly-determined device status (block 308). A new temperature target is then set (block 310), and the device continues to monitor temperature.

FIG. 4 is a flowchart showing yet another embodiment of this invention. This embodiment is based on the assumption that available battery capacity always decreases with a decline in temperature. As in the flowchart of FIG. 3, the device monitors temperature (block 400) and looks to see whether a temperature target has been reached (block 402). If so, the device determines whether there are valid temperature/status associations stored in memory (block 403). Stored associations may be invalid for many reasons, including age of the stored associations, recent use history of the device, etc. In a preferred embodiment, the device determines the validity of stored associations by determining whether the highest temperature stored in association with an indication of a warning device operational status is higher than the lowest temperature stored in association with an indication of a non-warning device operational status. The age of the stored associations are kept within 14 days by using only the last 14 associations stored, since the self-tests on which the associations are based are performed at a frequency no greater than once per day and since any postponement of a self-test invalidates the stored associations.

If the associations are valid, the device retrieves the associated device status from memory (block 406), indicates that status on the device status indicator (block 408), and sets the next temperature target (block 410). If, on the other hand, the stored temperature/status associations are not valid, the device ignores the stored temperature/status association and performs a battery capacity test (block 416) before indicating device status (block 408) and setting the next temperature target.

If there is no device operational status information stored in association with the target temperature, the device determines whether the target temperature is less than the lowest temperature stored in association with a non-warning (i.e., acceptable) device operational status (block 412). If not (i.e., if the target temperature is higher than a known non-warning temperature), based on the assumption that battery capacity

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increases with increasing temperature, the device indicates a non-warning status without performing a battery capacity test (block 420).

If the target temperature is less than the lowest temperature stored in association with a non-warning status but not greater than the highest temperature stored in association with a warning (i.e., unacceptable) device operational status (i.e., if the target temperature is cooler than a known warning temperature), the device indicates a warning status without performing a battery capacity test (block 422) based on the assumption that battery capacity decreases with a decrease in temperature.

It should be understood that, for purposes of this invention, the target temperatures may be temperature regions and not precise temperatures.

The following is a specific example of the methods of this invention as implemented in an external defibrillator such as defibrillator 10 in FIG. 1. In this example, the specified operating range for defibrillator 10 is 0° C. to 50° C. with the measurement accuracy being $\pm 2.5^\circ$ C. Defibrillator 10 maintains in device memory 21 a Recent Temperature History List (RTHL) containing the temperature reading and battery test results (e.g., "good battery" or "not good battery"; "warning" or "no warning"; etc.) for up to the most recent 14 battery capacity tests. The potential temperature measurements over the defibrillator's operating range are divided into bins as follows:

Temperature Range	Classification Bin #
>52.5 C.	8
[30.0 to 52.5] C.	7
[20.0 to 30.0] C.	6
[12.5 to 20.0] C.	5
[7.5 to 12.5] C.	4
[2.5 to 7.5] C.	3
[-2.5 to 2.5] C.	2
[-7.5 to -2.5] C.	1
<-7.5 C.	0

Temperature/status associations in the RTHL are invalidated whenever the defibrillator is actually used (i.e., when the device is placed in "use" mode) or when a battery is installed into the device since these actions can significantly alter the remaining battery capacity.

The algorithm assumes that the battery capacity always decreases with lower temperature and always increases or stays the same with higher temperature. In this example, defibrillator 10 is in a stand-by or power-down mode when it is not being used to treat a patient and is not running an automatic self-test. While in standby mode, defibrillator 10 checks temperature via its temperature sensor 20 every two seconds. When the defibrillator wakes up due to a temperature measurement at the high or low ends of its specified temperature range, the device will return to stand-by mode without any further tests. At the low end, the defibrillator will change the status indicator to indicate that the device is not ready to use.

If the present temperature is within the range of 0° C. to 50° C., the defibrillator extracts only the most recent valid battery capacity test result for each bin from the RTHL. If the present temperature bin (i.e., the bin encompassing the present ambient temperature) has not been tested and it is lower than the lowest passing bin and higher than the highest failing bin, the defibrillator runs its battery capacity test. Also, if the highest failing bin is higher than the lowest passing bin, the defibrillator runs its battery capacity test.

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Otherwise, the defibrillator sets the present battery capacity to reflect the previous test results from the RTHL without performing a battery capacity test: if the present bin is higher than a passing bin, the device indicates a "good battery" or non-warning status on its status indicator 22, and if the present bin is lower than a failing bin, the device indicates a "not good battery" or warning status on its status indicator 22.

In the preferred embodiment, the device sets both high and low target (or "wake-up") temperatures before returning to stand-by mode after a use, a self-test, etc. The following table illustrates how the HI and LO registers may be set:

Temp Target Registers	No Low Battery	Low Battery
Instrument	HI = Bin 8 (disabled)	HI = Bin 8 (disabled)
Temp in Bin 8	LO = Bin 7	LO = Bin 7
Instrument	if highest fail bin < lowest pass bin:	if highest fail bin < lowest pass bin:
Temp in		
Bins 2-7	HI = Bin 6 (disabled) LO = MAX (1 Bin lower than lowest pass, Bin 1) else:	HI = 1 Bin higher than highest fail LO = Bin 0 (disabled) else:
	HI = 1 Bin higher than present LO = 1 Bin lower than present	HI = 1 Bin higher than present LO = Bin 0 (disabled)
Instrument	HI = Bin 2	if no postponed tests and highest fail bin < lowest pass bin:
Temp in Bin 1	LO = Bin 0 (disabled)	
		HI = 1 Bin higher than highest fail LO = Bin 0 (disabled) else:
		HI = Bin 2 LO = Bin 0 (disabled)
Instrument	HI = Bin 1	HI = Bin 1
Temp in Bin 0	LO = Bin 0 (disabled)	LO = Bin 0 (disabled)

Target Bin #	Target Temperature
8	70 C. (disabled)
7	50 C.
6	25 C.
5	15 C.
4	10 C.
3	5 C.
2	0 C.
1	-5 C.
0	-55 C. (disabled)

FIG. 5 is a block diagram showing an external defibrillator that may be used to implement the methods of this invention. Many of the elements shown in FIG. 5 bear no relation to this invention. They have been included solely to show one context in which the invention may operate.

As mentioned above, while defibrillators are particularly appropriate for implementing this invention, the invention is not limited to use in defibrillators. In the defibrillator shown in FIG. 5, battery capacity tests are run daily as part of a suite of automatic self-tests, and the results are recorded in the RTHL. The timing of the tests may be such, however, that hour-to-hour ambient temperature fluctuations are missed. This invention therefore provides a way to take current temperature into account when providing a constant indication of device operational status.

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In defibrillator 100 of FIG. 5, the functions of the controller of the FIG. 1 defibrillator are distributed among an MPU 102 and two gate arrays 104 and 106. Gate array 106 also performs some of the functions of the self-test initialization generator of FIG. 1.

Gate array 106 monitors temperature every 2 seconds in stand-by mode via a temperature sensor 131 while the MPU and other parts of the device are inactive. In the embodiment shown in FIG. 5, temperature sensor is a thermistor, such as model no. AL03006-535K-145-G1 from Keystone. If the current temperature read by sensor 131 is equal to or warmer than a HI temperature target or equal to or colder than a LO temperature target (stored in registers in gate array 106), gate array 106 "awakens" the rest of the device (i.e., changes the device from stand-by mode to self-test mode), and power is provided to MPU 102 and gate array 104. At that point, MPU 102 determines the reason it was awakened by reading an ONOFF_REASON register within gate array 106.

If the reason was the reaching of a temperature target, MPU 102 looks to its own more accurate temperature sensor, AID temperature sensor 109 (such as an Analog Devices AD22100), to confirm the temperature. (While more accurate than sensor 131, sensor 109 requires more power than sensor 131 and is therefore only used when the device has been taken out of stand-by mode, as opposed to every 2 seconds as with sensor 131.) MPU 102 takes action appropriate to the new measured temperature, such as by looking to an RTHL stored in Flash ROM 114 to determine and indicate device battery status and by setting new temperature targets, as discussed above.

Any battery capacity test or other self-test called for by the method of this invention is run by MPU 102. Gate array 106 operates the device's visual status indicator 128 and beeper 119, which can function as an audible status indicator.

One consequence of using two different temperature sensors is the need for correlation between them. While the A/D temperature sensor 109 is sufficiently linear over the useful range of temperatures that might be encountered by the device, temperature sensor 131 is non-linear above 50° C. and below -10° C. A correction must be added to the sensor 131 temperature readings in the non-linear range to compensate for the non-linearity.

Modifications to the invention described above will be apparent to those skilled in the art. Such modifications are within the scope of this invention.

What is claimed is:

1. A method of indicating operational status of an external medical device, the device being capable of indicating operational status as a result of a self-test, the method comprising the following steps:

(a) monitoring an environmental condition of the external medical device; and

(b) changing an indication of device operational status from a first indication to a second indication if the monitored environmental condition changes from a first condition to a second condition,

wherein the changing step is performed without performing the self-test.

2. The method of claim 1 wherein the first indication is a non-warning indication and the second indication is a warning indication.

3. The method of claim 1 wherein the second condition is a target condition, the method further comprising the step of:

(c) setting a new target condition.

4. The method of claim 1 wherein the monitored environmental condition is a monitored temperature, the first condition is a first temperature and the second condition is a second temperature.

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5. The method of claim 1 wherein the external medical device is battery-operated and wherein the self-test that is not performed is a battery capacity test.

6. The method of claim 5 further comprising the steps of:

(c) performing the battery capacity test when the monitored temperature reaches the second temperature if there is no indication of device operational status corresponding to the second temperature stored in memory, the second temperature is lower than a temperature associated with an indication of a non-warning device operational status stored in memory, and the second temperature is higher than a temperature associated with an indication of a warning operational status; and

(d) indicating device operational status as a result of the battery capacity test.

7. The method of claim 6 further comprising the step of:

(e) storing in memory an association between the second temperature and device operational status.

8. The method of claim 5 wherein the battery-operated device is an external defibrillator.

9. The method of claim 1 further comprising the step of:

(c) changing the indication of device operational status from the second indication to the first indication if the monitored environmental condition reaches the first condition,

wherein the changing step is performed without performing the self-test.

10. The method of claim 9 wherein the environmental condition is temperature.

11. The method of claim 9 wherein the external medical device is battery-operated and wherein the self-test that is not performed is a test of battery capacity.

12. The method of claim 1 further comprising the step of:

(a)(i) retrieving from memory the second indication of device operational status the second indication of device operational status being associated with the second condition.

13. The method of claim 12 further comprising the step of:

(a)(ii) determining whether the second indication of device operational status is valid, the changing step being performed only if the second indication of device operational status is valid.

14. The method of claim 13 further comprising the step of:

(a)(iii) performing the self-test if the second indication of device operational status is invalid.

15. The method of claim 12 wherein the environmental condition is temperature.

16. The method of claim 12 wherein the external medical device is battery-operated and wherein the self-test that is not performed is a test of battery capacity.

17. The method of claim 1 further comprising the steps of:

(c) performing an automatic self-test when the monitored environmental condition reaches the second condition if there is no indication of device operational status corresponding to the second condition stored in memory; and

(d) indicating the device operational status as a result of the self-test.

18. The method of claim 17 wherein the environmental condition is temperature.

19. The method of claim 17 wherein the external medical device is battery-operated and the self-test that is not performed is a test of battery capacity.

20. The method of claim 17 further comprising the step of:

(e) storing in memory an association between the second condition and the device operational status.

* * * * *

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I. (a) PLAINTIFFS

KONINKLIJKE PHILIPS ELECTRONICS N.V.
and PHILIPS ELECTRONICS NORTH AMERICA
CORPORATION

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

CARDIAC SCIENCE, INC.

County of Residence of First Listed _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE
LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

Keith D. Petrak

Byrnes & Keller LLP

1000 Second Avenue, 38th Floor

Seattle, WA 98104 (206) 622-2000

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

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(For Defendant, place an "X" in One Box for Defendant)

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CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of <input type="checkbox"/> 160 Welfare Act <input type="checkbox"/> 170 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 180 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 190 Stockholders' Suits <input type="checkbox"/> 195 Other Contract <input type="checkbox"/> 195 Contract Product Liability	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury—Med. Malpractice <input type="checkbox"/> 365 Personal Injury—Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input checked="" type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 520 Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) SOCIAL SECURITY <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609
			FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 830 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Sanitization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) _____ ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

33 U.S.C. §§ 1 et seq. Patent infringement

VII. REQUESTED IN COMPLAINT:

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DEMAND \$

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JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions):

JUDGE

Hon. Thomas S. Zilly

DOCKET NUMBER

C03-1318Z

DATE
June 19, 2003

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